S. HRG. 100-766

# NATIONAL RESEARCH INSTITUTES REAUTHORIZATION ACT OF 1988

## HEARING

BEFORE THE

## COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

ON

## S. 2222

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REAUTHORIZE PROGRAMS RELATING TO THE NATIONAL RESEARCH INSTITUTES ESTABLISHED UNDER TITLE IV OF SUCH ACT, AND FOR OTHER PURPOSES

MARCH 29, 1988

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# NATIONAL RESEARCH INSTITUTES REAUTHORIZATION ACT OF 1988

TUESDAY, MARCH 29, 1988

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
*Washington, DC.*

The Committee met, pursuant to notice, at 2:42 p.m., in room SD-430, Dirksen Senate Office Building, Senator Barbara Mikulski, presiding.

Present: Senators Mikulski, Weicker, Harkin, and Hatch.

## OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. The Committee will come to order.

The purpose of today's hearing is to take testimony regarding the National Institute of Health's reauthorization.

We would like to welcome everyone to this afternoon's hearing. We would like to note that a cloture vote on high-risk notification will be beginning shortly. We thought it would begin at 2:30. We apologize to the witnesses for the delay and confusion, but we look forward to the testimony, and we might take some folks out of order, but it is to increase the flow of the hearing.

I am particularly pleased to be chairing these hearings on the reauthorization of the National Institutes of Health, not only because NIH is the premier medical research institution in the world today but, as the Senator from Maryland, the NIH holds even more significance for me with its 12,500 hard-working staff members.

The NIH is the largest employer in Montgomery County in the State of Maryland. Not only that, but Johns Hopkins University located in Baltimore is one of the world's most premier, preeminent research institutions and is one of the largest recipients of NIH grants.

The entire State of Maryland is fourth in receiving the Nation's NIH funds, but we don't view it as "pork barrel"; we look at it as an investment in America's future.

I am very proud to have such an esteemed institution as NIH in our home State. We are honored that NIH is there. We have multiple benefits not only for the State but our Nation.

At the same time, however, I am very concerned that we spend the money that we appropriate for the institutes wisely and well so that we may continue to take great pride in the accomplishments of NIH.

That is the purpose of this hearing—to understand how the NIH has been able to accomplish the great things it has and what it

might need to continue such a distinguished tradition of scientific excellence.

I would like to say that the NIH has improved the quality of life and in many ways extended life. Let me mention a few of the accomplishments of NIH research.

I know that you are developing a drug cure for childhood leukemia; demonstrating the cancer-causing role of asbestos in school construction; providing vaccines for life-threatening diseases such as rubella. And it is a great pride to the entire country that 88 recipients of the Nobel Prize have had their research supported in whole or in part by NIH.

I look forward to the testimony of both NIH staff and from the experts in the various fields who want to brief us.

I am going to ask that my statement be included in the record in its entirety, and also note that particularly as we listen to you, Dr. Wyngaarden, to you Drs. Hinshaw and Rosenberg, that an area of great concern to this Senator is workforce readiness; that both our contemporary needs in the delivery of health services and research, we know are quite pressing upon us now; but as we look ahead to the year 2000, one must wonder where are we going to get our scientists, will our scientists be able to afford to work in government, and will we be able to continue not only to win those Nobel Prizes, but to go for what they really represent, that America stands for the inventions not only of Star Wars, but how we can save lives and enhance life.

So, having said that, we want to move to our testimony.

First, however, we will include the full text of my opening remarks as well as statements by Senators Kennedy and Simon and the opening statements of Senators Weicker and Hatch.

[The prepared statements of Senators Mikulski, Kennedy, and Simon follow:]

BARBARA A. MIKULSKI
MARYLAND

United States Senate
WASHINGTON, DC 20510-2003

OPENING STATEMENT OF SENATOR BARBARA A. MIKULSKI
AT THE HEARING ON THE
REAUTHORIZATION OF THE NATIONAL INSTITUTES OF HEALTH
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
MARCH 29, 1988

I'D LIKE TO WELCOME EVERYONE TO THIS AFTERNOON'S HEARING. I AM PARTICULARLY PLEASED TO BE CHAIRING THESE HEARINGS ON THE REAUTHORIZATION OF THE NATIONAL INSTITUTES OF HEALTH, AND NOT SIMPLY BECAUSE THE NIH IS THE PREMIERE MEDICAL RESEARCH INSTITUTION IN THE WORLD TODAY. NO, FOR A SENATOR FROM MARYLAND, NIH HOLDS EVEN MORE SIGNIFICANCE--WITH OVER 12,500 HARD-WORKING STAFF MEMBERS, THE NIH IS THE LARGEST EMPLOYER IN MONTGOMERY COUNTY, MARYLAND. NOT ONLY THAT, BUT JOHNS HOPKINS UNIVERSITY, LOCATED IN BALTIMORE AND ONE OF THE WORLD'S MOST PREEMINENT RESEARCH INSTITUTIONS, IS THE LARGEST RECIPIENT OF NIH GRANTS. THE ENTIRE STATE OF MARYLAND IS FOURTH HIGHEST IN THE NATION FOR RECEIVING NIH FUNDS.

SO, I AM VERY PROUD TO HAVE SUCH AN ESTEEMED INSTITUTION BASED IN MY HOME STATE. AT THE SAME TIME, HOWEVER, I AM VERY CONCERNED THAT WE SPEND THE MONEY WE APPROPRIATE FOR THE INSTITUTES WISELY AND WELL, SO THAT WE MAY CONTINUE TO TAKE GREAT PRIDE IN THE ACCOMPLISHMENTS OF THE NIH.

THAT IS THE PURPOSE OF THIS HEARING--TO UNDERSTAND HOW THE NIH HAS BEEN ABLE TO ACCOMPLISH THE GREAT THINGS IT HAS, AND

WHAT IT MIGHT NEED TO CONTINUE SUCH A DISTINGUISHED TRADITION OF SCIENTIFIC EXCELLENCE. I CAN'T BEGIN TO DESCRIBE THE MULTITUDE OF WAYS THAT THE NIH HAS IMPROVED THE QUALITY OF LIFE, AND THE POSSIBILITY OF AN EXTENDED, HEALTHY LIFE FOR SO MANY, IN THE SHORT TIME WE HAVE TODAY. BUT LET ME JUST MENTION A FEW ACCOMPLISHMENTS OF NIH RESEARCHERS: DEVELOPING A DRUG CURE FOR CHILDHOOD LEUKEMIA; DEMONSTRATING THE CANCER CAUSING ROLE OF ASBESTOS IN SCHOOL CONSTRUCTION; PROVIDING VACCINES FOR LIFE THREATENING DISEASES SUCH AS RUBELLA; AND IMPROVING THERAPIES FOR CANCER, HEART DISEASE AND DIABETES. IT SHOULD BE A SOURCE OF GREAT PRIDE TO THE ENTIRE COUNTRY THAT 88 RECIPIENTS OF THE NOBEL PRIZE HAVE HAD THEIR RESEARCH SUPPORTED IN WHOLE OR IN PART BY THE NIH.

I LOOK FORWARD TO THE TESTIMONY OF BOTH NIH STAFF AND EXPERTS FROM MANY DIFFERENT FIELDS WHO WILL TALK TO US ABOUT THE NEED FOR NEW OR STRENGTHENED PROGRAMS AT THE NIH. IF WE ARE TO CONTINUE TO BE WORLD LEADERS IN THE AREA OF BIOMEDICAL RESEARCH AS WE ENTER THE 21ST CENTURY, WE MUST LOOK TO THE NIH TO BLAZE THE TRAILS THE WORLD WILL FOLLOW.

STATEMENT OF SENATOR EDWARD M. KENNEDY -- HEARING ON THE REAUTHORIZATION OF THE NATIONAL INSTITUTES OF HEALTH

In a hundred years of sustained excellence, the NIH has grown from a one room attic laboratory to the premier and largest medical research institution in the world today. The glory of the NIH derives from the truly impressive list of life-saving and life-enhancing medical breakthroughs this research has produced. Funding for NIH has not been money spent, but money invested, and every American has profited.

One only need look at the benefits that have accrued to children. NIH research has produced a drug cure for childhood leukemia, reduced mortality from neonatal respiratory distress syndrome, provided vaccines for life-threatening diseases such as rubella, developed early detection tests and treatments for congenital disorders that have saved thousands of children from mental retardation. Or one only need look at the benefits that have accrued to the aged. NIH research has resulted in the development of corneal transplants and laser retinal therapy that has saved the eyesight of many, as well as improved therapies for cancer, heart disease and diabetes. Yet, we are still far from the cures we seek for many dread diseases. And we are confronted with a new and deadly epidemic, AIDS.

Even as we need NIH more than ever, its progress is threatened. It's outstanding record of achievement has only been possible as a result of the federal government's willingness to share the cost of facility construction and maintenance at research institutions. This support was severely cut back after 1969, and financially constrained research institutions have been forced to defer needed construction and maintenance in order to keep up research productivity. In the reauthorization bill I have introduced today, I have proposed to institute a construction and revitalization grant program at NIH that will rebuild and expand our biomedical research infrastructure.

An increasing cause for alarm for the NIH campus itself is the strain being endured by the intramural program. Government salary caps are causing severe recruitment and retention problems; NIH senior scientists and Institute Directors are beckoned away by medical schools which offer to pay twice their maximum salary. A Senior Biomedical Scientist Service, which would be created by the reauthorization bill, will benefit senior scientists at NIH, FDA and CDC and at modest cost. I will also ask the Institute of Medicine to investigate the impact of establishing a publicly chartered National Institutes of Health foundation that might be a source of additional funds to augment the NIH budget.

My legislation will support a number of areas of research where there is particular promise. Medical rehabilitation research has brought much progress in the understanding and treatment of disabilities; yet it has not contributed to the extent it might for lack of an administrative focal point dedicated to its needs. I propose that a Center for Medical Rehabilitation Research be created at the NIH. I am also proposing the creation of a Centers for Biomedical Ethics program to be administered by the NIH. These Centers will provide guidance from ethicists and other experts as we confront the difficult choices that biomedical research is making possible. These are also exciting times for research on aging. We can capitalize on this momentum by authorizing the National Institute on Aging to establish centers in geriatric research and research training.

Another area of promise and need for emphasis is research on deafness and other communication disorders. This area is receiving increased public and congressional attention. I have proposed the funding of eight centers for research and training in deafness and other communication disorders by the National Institute of Neurological and Communicative Disorders and Stroke.

Training is also another important area of concern. I propose to reaffirm our commitment to research training by increasing the authorization level of the National Research Service Awards by 25 percent. This increase will allow for much needed substantial growth in the number of research trainees in the important areas of drug and alchohol abuse and mental health research. These disciplines are below the projected need as estimated by the National Academy of Sciences. The Chair of the President's Commission on AIDS has underscored the overarching importance of improving our research in the area of drug abuse.

In the last century a partnership has developed in biomedical research between government, academia and industry. The Federal support of NIH has made it preeminent in the world and we have been a steady and reliable partner. The reauthorization bill I have proposed will enhance the NIH's ability to play its role and will challenge our partners to match our commitment. I welcome the testimony of the distinguished witnesses who are here to testify on the NIH reauthorization.

STATEMENT OF SENATOR PAUL SIMON

before the

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

March 29, 1988

Mr. Chairman:

I would like to speak on behalf of reauthorization of the National Institutes of Health. The progress that we have made the area of health research, as well as the future progress on which the hopes of millions of Americans rest, depends on the level of commitment that we are prepared to make.

I thank the witnesses who have come here to provide us with their testimony. And I want to make special note of Dr. Ultmann's presence here today. Because of that, I'd like to focus the balance of my statement on the war on cancer.

Cancer used to mean certain death. Now, due to education efforts, the public has become aware of symptoms and self-testing procedures helpful in early detection. When cancer in

any of its many forms is detected quickly, the possibility of survival is greatly enhanced.

Many of the education programs which have helped raise general awareness of cancer have been disseminated by the National Cancer Institute. As awareness has spread, more patients have come forward to be treated while their prospects are still good. Physicians have been able to build on early diagnosis using new treatments to increase survivability.

Through public education and treatment research, NCI has effectively attacked cancer from two directions. In addition, by studying the environment and working conditions, NCI has been able to further reduce risks.

Breast cancer is a good example of the progress made by NCI. Available evidence is clear that increased use of breast cancer screening would considerably reduce the severe morbidity, premature mortality and treatment costs associated with advanced breast cancer. When detected early, there is a wider variety of treatment options than ever before.

Now that progress is being made in cancer research, we cannot let up. Further research into hereditary, environmental and lifestyle factors can reduce the incidence of cancer.

Simultaneously, new treatments can lead toward increased survival rates and a better quality of life.

Like the National Cancer Institute, the National Institutes on Aging, Child Health and Human Development, Allergy and Infectious Diseases, Dental Research, General Medical Sciences, Arthritis and Musculoskeletal and Skin Diseases, Diabetes and Digestive and Kidney Disease, Heart, Lung and Blood, Environmental Health Sciences, Neurological and Communicative Disorders and Stroke, National Eye Institute and National Library of Medicine have kept our nation on the cutting edge of health research. They need support from this body to continue their fine efforts.

Finally, it is my hope, that we can add to those a National Institute on Deafness.

The bill to establish a separate institute on communication disorders at NIH is potentially one of the most significant measures affecting those with hearing impairment to be considered in many years. I fully support Senator Harkin's bill, and appreciate his leadership on this matter.

Deafness and hearing disorders are often referred to as the "invisible handicap." And yet, there are more than 22 million

Americans who have disabling hearing conditions. There are an additional eight million Americans who have other significant communication disorders. We face a tremendous loss in human productivity and creativity as a result of our failure to fully address the problems of persons with communication disorders. Biomedical research support in deafness and other communication disabilities amounts to only two-tenths of one percent of the costs of communication disorders.

In correspondence with a Maryland physician who has a deaf daughter, in 1986 the Director of the Communicative Disorders Program at the National Institute of Neurological and Communicative Disorders and Stroke wrote: "Hearing impairment, unlike visual impairment, has never been able to secure enthusiastic public support. Possibly for this reason, and despite the ubiquity of hearing impairment, there is far less support available for research into hearing impairment than into support for visual impairment...Not the least of the benefits that would accrue from (an NIH research center on hearing impairment) would be heightened visibility of concern for hearing impairment generally, -- a problem often most aptly described as the 'invisible handicap.'"

I certainly would not argue that too much attention or too great an amount of funding is being expended for vision

research. It is greatly needed. But there is no question that attention and funding for vision research far surpasses that devoted to deafness and hearing impairment -- 1440 research grants last year for vision research in comparison to 400 in communications disorders. The existence of a National Eye Institute clearly has had the positive result of stimulating the development of grants and the focusing of attention on promising developments in research. A National Institute on Deafness can do the same for critical research in communications disorders.

We know that the population of those with hearing impairments in this country will grow substantially in the next ten years as a result of our aging population. We also know that problems of the ear are the most common disease of children between birth and age seven. At the same time, the number of workers in the field of deafness and communication disorders is increasing, and we are seeing important new discoveries in basic research that offer unprecedented hope for prevention, rehabilitation and treatment in the future. It is the time to act on these merging needs and opportunities, and the most effective action we can take is the establishment of a center to galvanize our efforts and to bring together the expertise and focused attention to make them grow.

Thanks to the superb efforts of the students at Gallaudet University recently, people who are deaf are no longer a silent, as well as invisible, part of our society. As we hear and accede to the demands for their right to dignity and equality, I hope we will also take the steps needed to make the wonders of science available to expand their opportunity. As a nation, we cannot afford to lose any of their great potential.

Thank you Mr. Chairman.

Senate Committee on Labor and Human Resources
Hearing on S. 1727, a bill to establish a
National Institute on Deafness and Communication Disorders.
Statement by Senator Paul Simon
March 29, 1988

I want to thank Senator Mikulski and my colleagues on the Committee for conducting this important hearing, and for permitting me to offer this statement for the record. The bill to establish a separate institute on communication disorders at NIH is potentially one of the most significant measures affecting those with hearing impairment to be considered in many years. I fully support Senator Harkin's bill, and appreciate his leadership on this matter.

Deafness and hearing disorders are often referred to as the "invisible handicap." And yet, there are more than 22 million Americans who have disabling hearing conditions. There are an additional eight million Americans who have other significant communication disorders. We face a tremendous loss in human productivity and creativity as a result of our failure to fully address the problems of persons with communication disorders. Biomedical research support in deafness and other communication disabilities amounts to only two-tenths of one percent of the costs of communication disorders.

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Senator MIKULSKI. The opening statements of Senators Weicker and Hatch will be inserted in the record at this point.

## OPENING STATEMENT OF SENATOR LOWELL P. WEICKER, JR.

Senator WEICKER. We are here today to hear testimony from many distinguished members of the biomedical research community about the reauthorization of the National Institutes of Health. As you all know, 1987 marked the centennial of NIH. However, I think that the members of this committee will agree that daily we celebrate its contributions to the health of our citizens and that of people throughout the world.

In recent years, Congress has stood firm in the face of proposed funding cuts and other legislative strategies that would have disarmed and even dismantled this vital contributor to our national security. It is with great pleasure that I join the members of the Labor and Human Resources Committee to consider the NIH reauthorization bill which will shortly be introduced. The bill will provide for the expansion of several vital research programs and improvements to the infrastructure of NIH which will strengthen the Institutes' ability to perform its research mission. Today we have an opportunity to strengthen NIH's capabilities by giving it new authority to deal with the pressures and challenges facing medical research today.

As the Nation contributes to battle AIDS, cancer, heart disease, diabetes, and other chronic illnesses and handicapping conditions, one thing is certain: You don't get exellence by waffling on the Nation's commitment to biomedical research. We need strong and consistent support of efforts to maintain and improve the bricks and mortar of our research facilities. And we must do everything we can to get rid of the climate of uncertainty already existing in the ranks of our researchers.

I look forward to hearing from our distinguished witnesses this afternoon, as they share with us their insights and concerns about the future of NIH. I am particularly interested in hearing about the problem of aging and obsolete facilities and instrumentation in NIH-supported institutions, the status of the NCI's war on cancer, and the need for an increased focus on research into both deafness and medical rehabilitation. I also look forward to hearing testimony on the factors that are affecting the Nation's medical manpower pool—the growing ranks of the elderly in America, the nursing shortage, the loss of research personnel to the private sector, and the lack of research training opportunities for medical rehabilitation physicians, physiatrists, surgeons, and others.

Finally, I want to commend Dr. Wyngaarden for his leadership at the NIH. It is my hope that the NIH reauthorization bill will enhance the ability of NIH to maintain its international prominence in biomedical research, and I look forward to working with my colleagues and the witnesses here today to achieve that goal.

## OPENING STATEMENT OF SENATOR ORRIN G. HATCH

Senator HATCH. It is always a pleasure to participate in hearings associated with the programs of the National Institutes of Health. I am from Utah and I understand the important role NIH has

played in our State—and let me describe some activities underway with NIH support at the University of Utah:

A miniature probe has been developed that combines the technology of micro chips with the field of electrochemistry. This probe, when inserted into a vein, will allow us to measure at the time of insertion, the chemical composition of the blood. The application of this technology goes beyond health care to other applications.

In addition, the university continues its work on the implantable artificial heart. Work is underway to develop a totally implanted, electronically powered heart by 1990.

These are only two of the many things that are underway at the University of Utah. The University of Utah has become a world leader in biomedical research under the able leadership of my good friend Dr. Chase Peterson with the support of funds from NIH.

The year 2000 is approaching and so is our rapid understanding of the science of health. We have completed a century of support for the work at NIH. And I am here today to lend support for the reauthorization of the National Institutes of Health into its second century.

NIH is a unique place. It is a Federal program that has had a great impact on medicine. It supports activities on campuses and beyond through its funding of research at universities and medical schools. It is clearly a bright star in the galaxy of medical research steering our efforts to find the cures and causes of disease around the world. NIH remains the crown jewel of the public health service.

I continue to be impressed with the breakthroughs in medicine that NIH has been involved with in the past and which continue today. NIH is on the cutting edge of technology in the research on cancer, dentistry, aging, AIDS, hypertension, heart disease, and one of NIH's newest research focuses on the center for nursing research. But I am especially impressed with the progress being made at the new National Institutes of Arthritis. You may remember Dr. Wyngaarden, you and I discussed this in this hearing room. At that time I asked you what you would do if Congress asked you to create this new institute. You responded that you would make it the best arthritis institute possible. And I am very pleased indeed that this is what is happening.

NIH is recognized for its contributions to medicine both in this country and internationally. This is reflected by the number of Nobel Laureates at NIH and the others supported by its grants and contracts across this country.

For example, in 1968 Dr. Marshall Nirenberg of the National Heart, Lung and Blood Institute received the Nobel for his work on cracking the genetic code. In 1986, the NIH supported research by Dr. Stanley Cohen of Vanderbilt University who won the Nobel for research on growth factors on nerve and skin cells, a major contribution in basic science. In 1987, Dr. Susumu Tonegawa at MIT received the Nobel Prize for his NIH-supported work in immunology.

Since 1945, the Nobel Prize has been awarded to 58 Americans in medicine. Of these 41 were either at the NIH or received support from the NIH. An additional 30 prizes were awarded for chemistry, 17 of those winners were either at the NIH or supported by its programs.

NIH is considered to be by young physicians and researchers the place to work in participating in advancing medical science.

Now, at the same time we are losing some of the best minds and most dedicated staff at NIH because of our inability to pay competitive salaries with universities and the private sector. This was made very apparent as recently as this month with the announcement that Dr. Marc Lippman, a noted oncologist at the National Cancer Institute, would be leaving to join the faculty of a local medical school at a significant increase in salary. I look forward today to discussing the problem of retention and recruitment and how proposals to establish a senior biomedical scientific service would solve this problem.

I look forward to hearing from all witnesses on proposals to improve NIH during its reauthorization. I am especially pleased to welcome Dr. Chase Peterson to the committee. Dr. Peterson has experience on NIH policies—both from medical academics and university administration. I look forward to hearing your views and all others here today.

Senator MIKULSKI. Dr. Wyngaarden, how much time do you think you need to make your presentation?

Dr. WYNGAARDEN. Madam Chairwoman, I think I can do it in about five minutes.

Senator MIKULSKI. You think you can do that in five minutes?

Dr. WYNGAARDEN. I can try, yes, ma'am.

Senator MIKULSKI. Well, I wish I would have had you in biology. [Laughter.]

Why don't you go ahead and make your presentation and then, is Dr. Rosenberg going to testify, or is he here for amplification on the work force issues?

Dr. WYNGAARDEN. He is here to respond to any questions you might have.

Senator MIKULSKI. Thank you. We will hear from you, Doctor, and then on to you, Dr. Hinshaw.

**STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD, ACCOMPANIED BY DR. STEVEN A. ROSENBERG, CHIEF OF SURGERY, NATIONAL CANCER INSTITUTE, NIH; AND DR. ADA SUE HINSHAW, DIRECTOR, NATIONAL CENTER FOR NURSING RESEARCH, NIH, BETHESDA, MD**

Dr. WYNGAARDEN. Thank you, Madam Chairwoman.

I am pleased to have this opportunity to discuss the reauthorization of expiring programs of the National Institutes of Health, to discuss the status of biomedical research facilities and the issue of pay and retention of senior scientists at the NIH.

NIH authorities expiring at the end of fiscal 1988 include programs for the National Library of Medicine, the National Research Service Awards Program, the advisory boards of the National Institute of Diabetes and Digestive and Kidney Diseases, and programs of the National Cancer Institute and the National Heart, Lung and Blood Institute.

First, a few words on the National Research Service Awards.

Since the inception of NIH, the interdependence of research training and research has been recognized. This linkage provides an opportunity for new discovery and development of the next generation of scientists to occur in the same laboratories. The NIH Research Service Awards serve several functions. They provide an opportunity for students to pursue research careers; they enhance research environments, and most of all, they support the Nation's research enterprise by ensuring the flow of well-trained young scientists into research careers.

Between 10,000 and 11,000 NRSA positions are supported by NIH each year, with approximately equal numbers of pre- and postdoctoral positions. Most predoctoral positions are Ph.D. traineeships, and more than half the postdoctoral traineeships support M.D.s.

With the dynamic expansion and sophistication of biomedical research, there continues to be a need to provide adequately trained manpower to answer the important research questions. At the same time, with the total number of graduates declining, commensurate falling enrollments in fields of study related to biomedical sciences, and pressures to pursue lucrative non-research careers challenge us to assure a steady supply of manpower into biomedical research.

With respect to the Medical Library Assistance Act, effective biomedical information services are essential if we are to attain the maximum benefits from our investment in research and treatment of major human afflictions. The programs authorized by the Medical Library Assistance Act and administered by the National Library of Medicine form the foundation for much of the work in providing this assurance. Since passage of the MLAA in 1965, NLM has assisted health science libraries throughout the country to establish, expand and improve their information services.

There are other expiring authorities, also. Three other NIH authorities that need to be reauthorized include the mandate for the National Advisory Boards of the National Institute of Diabetes, Digestive and Kidney Diseases and authorizations of appropriations for National Heart, Lung and Blood Institute and the National Cancer Institute.

The Administration is developing legislation related to NIH's expiring authorities.

Beyond our expiring authorities, Madam Chairwoman, we understand that the Committee wishes us to address biomedical research facilities and senior staff recruitment and retention.

There have been many expressions of concern both to the Congress and NIH regarding the substantial need for new biomedical research facilities and for repair and renovation of deteriorating facilities. There have been major advances in the volume and quality of the scientific knowledge base, and new technologies and scientific opportunities are developing rapidly.

Special requirements for protection of research workers and the public from biological and chemical hazards and increased security needs have placed greater demands on our existing facilities. There are continued needs for alteration and renovation of laboratory animal facilities, as well as an inevitable backlog of repairs and remodeling of aging and deteriorating facilities.

Consideration of Federal support for construction of biomedical research facilities was requested by the House and Senate Appropriations Committees in their report on the 1988 budget. NIH was asked to "convene a group of consultants to make recommendations on the design, balance and administration of a pilot research facilities program to assist universities and nonprofit research institutions in replacing obsolescent biomedical research facilities and equipment."

On February 9 and 10, 1988, an ad hoc study group of leaders of colleges, universities and nonprofit research institutions was assembled by NIH to address issues related to research facilities construction. We are preparing a report on the recommendations of the study group, and two members of that study group are prepared to testify later.

Finally, with respect to senior-level recruitment and retention. Concerns have been raised about recruitment and retention of researchers on the NIH campus. Recruitment and retention problems as well as limitations on the number of senior level positions have resulted in critical vacancies and deferred recruitment.

Recruiters from academia and industry make highly attractive offers that at best are unsettling and all too often are successful.

Academic institutions, industry and independent research laboratories offer substantial salary increases. Compensation of physicians and other doctorates in academic institutions is considerably higher than at NIH.

In the academic sector, on the average, the compensation of senior physicians is 62 percent higher than that received by NIH senior physicians, while the base pay of senior Ph.D. staff is 23 percent higher than that received by NIH senior Ph.D. staff.

Employment in the academic sector provides the prospect of superior salary supplements, fringe benefits such as tuition subsidies, and better opportunities to supplement income through private practice and consultation.

If NIH is to remain the international leader in the biomedical sciences, new approaches must be found to make our senior level personnel systems competitive with the private and academic centers. At the request of OMB, we have asked the Institute of Medicine to study the structure and organization of NIH intramural research, including recruitment and retention difficulties, their causes and effects on NIH research quality, and potential strategies to address them if warranted. That study is about to begin. A chairman of the committee has been selected, and they have been asked to report in about six months. We would like to study the IOM findings and recommendations before we make final recommendations on recruitment and retention issues.

Madam Chairwoman, that concludes my prepared statement. I would be pleased to answer any questions you may have.

[The prepared statement of Dr. Wyngaarden and responses to questions submitted to the panel by Senator Hatch follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 1
Room : 124
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APR 2 0 1988

The Honorable Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Dear Senator Kennedy:

I would like to request that the Committee make a change in the written statement submitted for the record at the NIH reauthorization hearing on March 29.

Estimates made by the National Academy of Sciences for the National Science Foundation indicate that 101,800 life scientists were employed in the United States in 1985, up from 92,800 in 1983 and 63,000 in 1975. Since preparing the testimony we have learned that the previous figures, which appear on page 2 of the statement, presumably represented estimates for scientists and engineers working in all fields in the United States.

Enclosed is a complete, corrected version of the statement. There is also a minor revision on page 4 regarding the President's budget request for the National Center for Biotechnology Information. We would be most appreciative if these changes were accepted by the Committee. Thank you for your assistance.

Sincerely yours,

James B. Wyngaarden

James B. Wyngaarden, M.D.
Director

Enclosure

STATEMENT

BY

JAMES B. WYNGAARDEN, M.D.

DIRECTOR

NATIONAL INSTITUTES OF HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

U.S. SENATE

MARCH 29, 1988

Madam Chairwoman and Members of the Committee:

I am pleased to have the opportunity to discuss the reauthorization of expiring programs of the National Institutes of Health, the status of biomedical research facilities, and the issue of pay and retention of senior scientists at NIH.

NIH authorities expiring at the end of fiscal year 1988 include programs of the National Library of Medicine, the National Research Service Awards Program, the advisory boards of the National Institute of Diabetes and Digestive and Kidney Diseases, and programs of the National Cancer Institute, and the National Heart, Lung, and Blood Institute.

NATIONAL RESEARCH SERVICE AWARDS

Since the inception of NIH, the interdependence of research training and research has been recognized. This linkage provides an opportunity for new discovery and development of the next generation of scientists to occur in the same laboratories. The National Research Service Award (NRSA) programs serve several functions: they provide an opportunity for students to pursue research careers, they enhance research environments, and most of all, they support the nation's research enterprise by ensuring the flow of well-trained young scientists into research careers. Between 10,000 and 11,000 NRSA positions are supported by NIH each year, with approximately equal numbers of pre- and

postdoctoral positions. Most predoctoral positions are Ph.D. traineeships. More than half the postdoctoral traineeships support M.D.'s. In addition, NRSAs are supported by the Alcohol, Drug Abuse, and Mental Health Administration and by the Health Resources and Services Administration.

Section 487(d)(3) of the Public Health Service Act requires that half of one percent of NRSA funds be made available for research training in primary care. In FY 1988, NIH will award more than one-half percent of NRSA funds for institutional training grants related to primary care research training in the areas of pediatrics, family practice, internal medicine, dentistry, and mental health. These funds will be awarded to grant applications received in response to our direct solicitation to increase efforts in this area.

With the dynamic expansion and sophistication of biomedical research, there continues to be a need to provide adequately trained manpower to answer the important research questions. At the same time, with the number of graduates in total declining, commensurate falling enrollments in fields of study related to biomedical science and pressures to pursue lucrative non-research careers challenge us to assure a steady flow of manpower into biomedical research. The number of employed biomedical scientists has been increasing--101,800 life scientists were working in 1985, up from 92,800 in 1983 and 63,000 in 1975. Continued support of NRSA awards, as proposed in the President's FY 1989 budget, would add more biomedical researchers to this pool.

MEDICAL LIBRARY ASSISTANCE ACT

Effective biomedical information services are essential if we are to attain the maximum benefits from our investment in research and treatment of major human afflictions. The programs authorized by the Medical Library Assistance Act (MLAA) and administered by the National Library of Medicine form the foundation for much of the work in providing this assurance. Since passage of the MLAA in 1965, NLM has assisted health science libraries throughout the country to establish, expand, or improve their information services.

Although results have been impressive, continued growth in the biomedical literature and the increasingly interdisciplinary nature of scientific research require that health professionals have access to a very wide range of information from many different sources. An even stronger, more technically advanced communications network to provide effective access to all that information is essential. Our nation's medical libraries must have available the latest information technologies, equipment, and services to aid health care professionals. The NLM's library assistance programs help provide the means, and represent the only direct Federal assistance programs focused on this effort. The President's FY 1989 budget seeks $ 9.790 million for this program, up from $ 9.414 million in FY 1988. In total, the President's FY 1989 budget seeks a 4-percent increase for the NLM, up from $67.9 million in FY 1988 to $70.6 million in FY 1989.

Biotechnology, as a new field, has special requirements for information handling. To reap the potential benefits of research in this field and

harness the biotechnology information that is being generated by the nation's laboratories, the National Library of Medicine will spend $3.8 million in FY 1988 on the National Center for Biotechnology Information, which will coordinate and integrate the form and content of the databases in this area and provide for distribution of biotechnology data via electronic means. Approximately $4 million is proposed for FY 1989 in the President's budget request. The work of this Center will be crucial in the forthcoming research on sequencing and mapping the human genome.

OTHER EXPIRING AUTHORITIES

Three other NIH authorities are expiring at the end of the fiscal year: the mandate for National Advisory Boards of the National Institute of Diabetes and Digestive and Kidney Diseases and the authorizations of appropriations for the National Heart, Lung, and Blood Institute and the National Cancer Institute. The NIDDK boards serve an important long-range planning function, provide a framework for interagency dialogue and cooperation, and serve as an expert source of advice for NIH and the Department. The NHLBI combines a balance of basic, clinical, and applied research; research training; and demonstration and education activities that have contributed to the health and well-being of the nation. The NCI continues its commitment to the support of basic research, which is the basis of the Institute's treatment research and prevention studies involving dietary and lifestyle changes. The Administration is developing legislation related to NIH's expiring authorities.

Madam Chairwoman, we are concerned with the proliferation of institute-level components within the NIH. In 1984, the Institute of Medicine (IOM) issued a

report dealing with the organizational structure of the National Institutes of Health. The IOM committee found the evidence about the desirability of organizational change at NIH to be mixed, in part because such changes may add significant administrative costs without ensuring increased resources for the research effort. In viewing NIH's organizational development, the IOM concluded that "NIH has reached a point at which there should be a presumption -- to be overridden only in exceptional circumstances — against additions at the institute level." As an alternative, the IOM recommended that NIH "should avail itself of a range of activities, short of establishing new institutes, to respond to health needs and opportunities."

In these times of fiscal restraint, it is more productive to focus our attention on expanding the broad base of existing research. Monies that would be needed for startup and continued administrative costs for large new units could be more efficiently used in support of research. The Department of Health and Human Services believes the creation of additional NIH institutes and centers should be viewed with caution.

Beyond our expiring authorities, we understand that the Committee wishes us to address biomedical research facilities and senior staff recruitment and retention.

BIOMEDICAL RESEARCH FACILITIES

There have been many expressions of concern both to the Congress and NIH regarding the substantial need for new biomedical research facilities and for

repair and renovation of deteriorating facilities. There have been major advances in the volume and quality of the scientific knowledge base, and new technologies and scientific opportunities are developing rapidly. Special requirements for protection of research workers and the public from biological and chemical hazards and increased security needs have placed greater demands on our existing facilities. There are continual needs for alteration and renovation of laboratory animal facilities, as well as an inevitable backlog of repairs and remodeling of aging and deteriorating facilities. Some facilities should not be repaired or renovated, but completely replaced.

We are studying the adequacy of existing research facilities, as well as the extent of need for renovation and improvement of inadequate facilities by our universities. As you know, Federal agencies expend several hundred million dollars annually for university research facilities through overhead charges. The National Science Foundation (NSF) and NIH have surveyed university administrators on the condition of research facilities. NSF data published in Science and Engineering Research Facilities at Doctorate-Granting Institutions (Sept. 1986) indicated that universities have planned or begun substantial construction and renovation projects. NSF is collecting additional data on existing and planned university facilities, to be published in the fall of 1988.

Consideration of Federal support for construction of biomedical research facilities was requested by the House and Senate Appropriations Committees in their reports on the FY 1988 budget (S.Rept.No. 100-189; H.Rept. 3058). NIH was asked to "convene a group of consultants to make recommendations on the

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design, balance, and administration of a pilot research facilities program to assist universities and nonprofit research institutions in replacing obsolescent biomedical research facilities and equipment." On February 9-10, 1988, an ad hoc study group of leaders of colleges, universities, and nonprofit research institutions was assembled by NIH to address issues related to research facilities construction. We are preparing a report on the recommendations of the study group.

SENIOR LEVEL RECRUITMENT AND RETENTION

Concerns have been raised about recruitment and retention of researchers on the NIH campus. Recruitment and retention problems as well as limitations on the number of senior level positions have resulted in critical vacancies and deferred recruitment. A great many highly motivated senior staff have elected to remain at NIH, but recruiters from academia and industry make highly attractive offers that at best are unsettling, and only too often are accepted. While the Senior Executive Service (SES) allows NIH to promote some of our most accomplished scientists and administrators into the senior ranks, we have had limited success in attracting top caliber candidates from outside the Government. Academic institutions, industry, and independent research laboratories offer substantial salary increases. Compensation of physicians and other doctorates in academic institutions is considerably higher than that available at NIH. In the academic sector, on the average, the compensation of senior physicians is 62 percent higher than that received by NIH senior physicians, while the base pay of senior Ph.D. staff is 23 percent higher than that received by NIH senior Ph.D. staff.

At the same time, the NIH offers advantages that for many researchers offset the salary differentials. Among these are the intellectual stimulation and prestige of being a part of NIH, as well as the scientific freedom to choose their own research pursuits. Scientists at NIH have access to state-of-the-art equipment, freedom from administrative and teaching responsibilities, and opportunity for rewarding associations with outstanding scientists from many disciplines. Also, there are opportunities for consulting, although these are subject to some limitations.

Employment in the academic sector provides the prospect of superior salary supplements, fringe benefits such as tuition subsidies, and better opportunities to supplement income through private practice and consultation. In addition, the fact that there is no limit upon university salaries supported through NIH extramural mechanisms further fuels the pay competition from the academic sector.

Recent advances in the biomedical sciences and biotechnology have opened many potentially valuable and lucrative commercial applications and have caused a dramatic increase in competition for top caliber researchers and science managers in the private and academic sectors. The emergence of the biotechnology industry has contributed to the competition between senior NIH staff and their counterparts in industry and universities.

Recruitment and retention of intramural scientists should be viewed in the context of training. As a training ground for post-doctoral researchers, the intramural laboratories of NIH have helped staff the Nation's research

universities. Many junior scientists complete their training at NIH and continue their research careers in the universities. A high percentage of this country's leading researchers are NIH alumni.

If NIH is to remain the international leader in the biomedical sciences, new approaches must be found to make our senior level personnel systems competitive with the private and academic sectors. We have asked the Institute of Medicine to study the structure and organization of NIH intramural research including recruitment and retention difficulties; their causes and effects on NIH research quality; and potential strategies to address them if warranted. We would like to study the IOM findings and recommendations before we make final recommendations on recruitment and retention issues. Further, we are in the process of implementing the provisions of Public Law 100-140, which extended and doubled the maximum PCA allowance.

Madam Chairwoman, that concludes my prepared statement. I would be pleased to answer any questions you may have.

Questions by Senator Hatch

Responses to Questions
from the
Senate Committee on Labor and Human Resources

Question

Do you feel the establishment of a senior scientist service would help to keep researchers at NIH and other public health agencies, including FDA and ADAMHA?

Answer

I feel that the establishment of such a service would substantially improve our ability to keep top caliber senior researchers and scientist administrators in the Public Health Service agencies. Speaking only for NIH, we have encountered considerable difficulty recruiting and retaining senior level scientists and researchers over the last decade. These problems have grown more severe during the last several years as the competition for biomedical scientists has increased and the gap in compensation between the Government and the academic and private sectors has widened. Unfortunately, our senior level personnel systems have not kept pace with this competition. If this situation continues, I am concerned about our ability to maintain the excellence of the NIH intramural programs.

Last year, in recognition of this problem, the Office of the Secretary, HHS, initiated discussions with representatives from NIH, FDA, CDC, and ADAMHA to identify possible solutions. This resulted in the development of a proposal to establish a Senior Biomedical Research Service as an alternative personnel system for senior level science administrators and researchers. The proposal has been forwarded to the Office of Management and Budget and is pending. NIH has also asked the Institute of Medicine to study the structure and organization of our intramural program, including the problem of recruiting and retaining senior level scientists; their effects on NIH research quality; and potential alternatives to address them if warranted.

In my opinion, a new senior level personnel system such as the Senior Biomedical Research Service is very much needed and would be a major step towards alleviating many of the recruitment and retention problems we have been experiencing.

Question

A great deal has been written lately about recruitment and retention problems in the intramural program, especially after OMB made the proposal to "privatize" the NIH. Is this program in significant danger of losing its world-class stature?

Answer

Increasingly, the NIH intramural program is becoming less and less competitive in the salaries it can offer to senior scientists, compared with the nation's medical schools, which comprise its principal private sector counterpart. Thus, as younger NIH trainees mature into scientists of repute, they may be recruited away, and it is almost impossible to attract a senior level person from the outside into the NIH. The "compensation gap" at the senior levels (equivalent to full professor and above), if allowed to continue unchecked for a prolonged length of time, will undoubtedly adversely affect the quality of the NIH scientific leadership and the stature of its intramural program.

Question

Dr. Rosenberg, I am pleased that you are still at NIH. However, could you please tell me what kind of offers to leave NIH you and your colleagues receive and how they compare with the compensation and other benefits at NIH?

Answer

The National Institutes of Health is the premier research institution in the world, and I consider it a privilege to work there. There are, however, major problems that are making it increasingly difficult to recruit and obtain high quality clinical and scientific staff. The salaries for clinical scientists at the National Institutes of Health are far below those in virtually any U.S. medical school and certainly far less than exists in many clinical practice opportunities. In addition to this low salary, the ancillary financial benefits such as tuition allowances for children's education are also far less. Many senior staff are forced to leave the NIH at a time when their children are ready to attend college. This often occurs when these clinicians are in their mid to late forties, a time when their productivity and clinical and scientific contributions are at their peak.

During the past five years I have received approximately eight requests from search committees to consider positions as Chief of Surgery at major medical schools in the United States. The salary range for these positions varied from about $170,000 to $260,000 a year. In addition, I have received two requests to consider appointments as the Director of a Cancer Center at major universities with salaries comparable to those listed above. This compares to my salary at the National Institutes of Health which is approximately $80,000 a year. Many of these positions come with other benefits, such as special programs to pay part or all of tuition for education of children, retirement and health benefits.

Other members of our senior staff also receive offers that far exceed their NIH salaries. For example, Dr. Jeffrey A. Norton, a Senior Surgeon in the Surgery Branch of the NCI has received two offers during the past year to be a Professor of Surgery at major U.S. medical schools. These offers were at salaries of $180,000 and $220,000 a year respectively. One of our urologists, Dr. Cary N. Robertson has received several offers to join the faculty of the university medical schools or to join large private practice groups with salaries in the range of $200,000 a year. The head of our Thoracic Surgery group in the Surgery Branch has also received offers to join the faculty of other U.S. medical schools, at salaries similar to those mentioned above.

Question

Dr. Wyngaarden, NIH and the Nation clearly benefit not only from the research done at the NIH but also from that done at the "universities around the country. What is the Administration position on the provisions of this bill to address the need for a research facilities construction program?

Answer

At present, we do not have a Department position. The complex issues associated with research facilities construction are under review.

Certainly, we appreciate the interests of the Committee in providing for the development of an adequate research facilities infrastructure to support the continual biomedical research progress and scientific breakthroughs going on in our academic and nonprofit research institutions. We share the opinion that there is a need for a long-range coordinated strategy to maintain the excellence of our biomedical research capability. The question is, of course, what share of this need the Federal Government can be expected to assume in providing for a dependable and long-term flow of funds for new construction, renovation of facilities, and replacement of equipment, given the fiscal restraints within which we must operate for supporting biomedical research projects.

Question

Dr. Wyngaarden, are we in a position that the condition of our research facilities in this nation is placing this country at a disadvantage in the international research community?

Answer

There have been many concerns expressed by the biomedical research community that the Nation may be losing ground in maintaining the excellence of its biomedical research capability because of problems in modernizing facilities, replacing obsolescent equipment, and keeping up with the rapid development of scientific technologies and opportunities. Certainly, any erosion in our science base could have far-reaching effects and implications both for the future conduct of research in the United States and in the arena of intense international competition.

Question

Some Members of Congress are dubious about whether a real need exists to spend millions of dollars on the renovation of research facilities. They are also doubtful that we need more research space, given the rapid rate of progress in medical research in recent years. What do you have to say to them?

Answer

Resource requirements are necessary for scientific progress. Adequate facilities and equipment to conduct biomedical research is essential. In addition, the facilities must be in compliance with established standards and the institutions must be prepared to respond to new leads and developments in the knowledge base.

There have been many major advances in the volume and quality of the scientific knowledge base. There has been an unprecedented pace of growth in recent years. Unanticipated challenges, for example, in molecular and cellular biology, genetic, and immunology, with concomitant expectations for continued expansion of this knowledge base, must be met as they arise.

New technologies and scientific opportunities are developing rapidly (e.g., magnetic resonance imaging, spectroscopy, x-ray crystallography, etc.). These have attendant expanded needs for sophisticated equipment and the facilities to contain them. Special requirements for protection of research workers and the public from biological and chemical hazards and increased security needs have placed greater demand on our existing facilities. There are continual needs for alteration and renovation of laboratory animal facilities, as well as an inevitable backlog of repairs and remodeling of aging and deteriorating facilities. Some facilities should not be repaired or renovated, but completely replaced.

We are studying the needs and the adequacy of existing research facilities through a survey co-sponsored by the National Science Foundation and the NIH.

Question

Will the facilities construction authority which would be established by the NIH reauthorization bill provide adequately for the needs you have described?

Answer

With construction authority, the NIH could provide leadership for a well-coordinated, long-range strategy at the Federal level to address the critical construction needs in a timely and effective manner. We could also provide a stimulus role for the institutions to attract private sector support from foundations and industry.

Question

Many have expressed concern about the "have not" institutions and whether they will benefit at all from a program like this. Do you believe there is a problem with "have not" institutions? What do you think we should do about this?

Answer

We would hope to be able to add to the existing strengths of institutions of emerging excellence. Our intention is to invest in capable institutions that have already demonstrated a commitment to addressing the needs of the underrepresented in the health sciences to enhance and expand their research quality and productivity.

We also recognize that some Federal support should be provided to institutions that have capabilities to train faculty, study diseases and health conditions that disproportionately affect Blacks and other minorities, and have research efforts already underway or planned to such an extent that the ability to carry out the plan is evident.

Possibly, construction needs could be identified that are of such high priority that the Federal Government could increase its share of participation in providing resources should adequate funds be made available. This would have to be determined on a case by case basis under the merit and peer review criteria established by NIH program guidelines.

Question

There has been considerable activity in the deaf community to stimulate increased emphasis on this area of research. How is the NIH responding to this request and how can Congress best assist the NIH in meeting this challenge?

Answer

Hearing and communication research is conducted within the National Institutes of Health (NIH) primarily by four institutes, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), the National Institute of Child Health and Human Development (NICHD), the National Institute of Dental Research (NIDR), and the National Institute on Aging (NIA). These components of the NIH support studies of deafness and auditory prostheses, auditory impairment in the young and old, prevention and treatment of hearing loss, speech perception, communicative aids, stuttering, children's language disorders, aphasia, the assessment of vocal pathologies, and speech prostheses. In addition to the substantial amount of existing research, several initiatives have been planned by the NIH.

- NIH has pioneered in the development of modern hearing aids, which are small, lightweight, battery-operated, and easy to use and maintain. In addition, they are constantly being improved to meet the specific needs of the user.

- Perhaps the most promising and exciting device under development is the cochlear implant, which uses tiny electrodes to apply electrical stimulation to auditory nerve fibers. Plans are currently under way for an NIH Consensus Development Conference on Cochlear Implants, May 2-4, 1988. The conference is sponsored by the National Institute of Neurological and Communicative Disorders and Stroke, the NIH Office of Medical Applications of Research, the National Institute on Aging, the National Institute of Child Health and Human Development, the Veterans Administration, and the Food and Drug Administration.

- The NINCDS is developing a Request for Proposal (RFP) to address the questions of implantation and explanation of cochlear implants.

- The NINCDS has sent out two recent Program Announcements in an effort to generate additional grant applications in areas of need. The two recent announcements, PROGRESSIVE HEARING IMPAIRMENT and SWALLOWING DISORDERS, have been issued to stimulate investigators to address unresolved problems in these areas.

- The NIA commissioned the National Academy of Sciences' Committee on Hearing, Bioacoustics, and Biomechanics to (1) evaluate the elderly listener's ability to understand speech and (2) identify areas of scientific inquiry needed to elucidate the underlying physiological and cognitive mechanisms mediating age-associated changes in hearing and speech comprehension. A report of their findings will be published in the Journal of the Acoustical Society of America this year.

- The NIA issued a program announcement addressing hearing and communication disorders in the elderly in FY 1987. The NIA is planning a workshop in FY 1988 on needs in geriatric otolaryngology research and training, cosponsored by the American Academy of Otolaryngology, Head and Neck Surgery, followed by a program announcement on support for training in geriatric otolaryngology research.

- The NIA and NINCDS will co-sponsor a program announcement on chemosensory aging.

The approximate funding levels for the institutes in FY 1987 were NINCDS, $61,237,000; NICHD, $7,415,959; NIDR, $3,655,000; and NIA, $1,496,000, totaling approximately $73.8 million. The program areas of deafness and communication are receiving appropriate allocation of resources and attention within the NIH. NINCDS has increased funding for hearing and communciation research from $50,661,000 in FY 1985 to approximately $61,237,000 for FY 1987. NICHD has almost doubled funding from $4,189,049 in FY 1985 to $7,415,959 in FY 1987. NIDR has increased funding from $2,866,000 in FY 1985 to $3,655,000 in FY 1987, and NIA from $733,000 in FY 1985 to $1,496,000 in FY 1987. Hearing and communication research has received in the past, and continues to receive a high priority status within the NIH. With the support of Congress, the NIH will continue to make great progress in the area of hearing and communication research.

Question

Dr. Hinshaw, there is a provision in this bill to provide the National Center for Nursing Research with authority to fund demonstrations in nursing research, specifically in the areas of recruitment and retention of nurses. Is this provision necessary, especially in light of title VIII of the PHS Act and the programs funded by the Health Resources and Services Administration's Division of Nursing?

Answer

Under its authority in title VIII to support demonstration projects and nursing education programs targeted for special purposes, demonstration projects concerned with the health services aspects of nursing manpower availability and education are appropriately carried out by the Division of Nursing, HRSA. The National Center for Nursing Research (NCNR), from the research perspective of its mission, would apply demonstration authority in a broader sense as a transfer mechanism for nursing research findings based in a diversity of settings, including the home, the nursing home, the public health clinic and other ambulatory care facilities, as well as the hospital. In the course of demonstrating what has already been investigated, it should be possible to test new approaches to nursing practice that would include both biological and behavioral parameters; e.g., nursing interventions during rehabilitation following cardiac surgery or cancer therapy. It could also be used as a vehicle for demonstrating research findings on innovative models of care, such as the continuity of care concept, which is based on coordinated care across settings or a continuous nurse-patient relationship across settings. Using the demonstration model to test and transfer research findings on the nurse's role in patient care, could be helpful in improving the quality of the nursing role.

The NCNR and the Division of Nursing, HRSA, have just initiated a collaborative effort for research and demonstration projects on an innovative practice model for restructuring nursing resource management and delivery of patient care methods. This collaboration will use the expertise and authorities of both agencies. The purpose of the project is to develop, implement and study replicable nursing care delivery models in hospitals to test approaches for increasing available nursing resources and influencing quality care, and will include consideration of cost and benefit.

Question

Do you feel that the demonstration authority proposed in the NIH reauthorization bill will lead to a useful exploration of the quality of the nursing role? Do you feel there is a direct connection between the quality of the nursing role and the quality of patient care? Will research in this area be of benefit to patients?

Answer

The demonstration model could be employed by the National Center for Nursing Research (NCNR) as a transfer mechanism for nursing research findings based in a diversity of settings, including the home, the nursing home, the public health clinic and other ambulatory care facilities, as well as the hospital. In the course of demonstrating what has already been investigated it should be possible to test new approaches to nursing practice that would include both biological and behavioral parameters; e.g., nursing interventions during rehabilitation following cardiac surgery or cancer therapy. The demonstration model might also be used as a vehicle for demonstrating research findings on innovative methods of care, such as the continuity of care concept, which is based on coordinated care across settings or a continuous nurse-patient relationship across settings. By using the demonstration model to test and transfer research findings on the nurse's role in patient care, it could be useful to improving the quality of the nursing role.

Nurses are with patients twenty-four hours a day. There are aspects to nursing that are different from other medical personnel needs and much that is complementary in a very basic sense to other biomedical and clinical activity. The elements that facilitate or hinder nursing care affect the quality of clinical care that is provided to the patient in many settings, including the home. Nurses care for the critically and the chronically ill, work with those who are well to maintain their health, and work with those at health risk to prevent or ameliorate their risk. Assuring and improving the quality of the nursing role through the use of research findings could affect the quality of patient care.

Question

How serious is the national nursing shortage? How do you view the role of the National Center for Nursing Research in addressing this problem?

Answer

Although there has not been an actual decline in the number of registered nurses, there has been and continues to be an increase in the demand for nursing services. This situation, which has created an imbalance between the availability of nurses and the demand for nursing services, has produced what is being described as a nursing shortage. Hospitals, the principal employer of nurses, have been the most severely affected by this situation. Upwards of 13 percent of budgeted positions in hospitals reportedly are vacant. Individual hospitals have closed beds and in some cases whole units. Home health care agencies, nursing homes, and other types of health care facilities are also reported to have similar problems, but there is little organized data to support this. In addition, schools of nursing are reporting a decline in applicants and enrollments.

There have been both regional and national shortages of nurses in the past; however, there has not been a companion decline in enrollments. Because the current problem is coupled with an apparent decline in numbers of those entering the field (as those who have historically gone into nursing choose other options), the present situation portends a deeper and more long lasting problem than in the past and may curtail the ability of hospitals and other health care agencies to provide safe and efficient patient care.

Research on the availability and influence of nursing resources on effective patient care is of concern to and within the mission of the National Center for Nursing Research (NCNR). In fiscal year 1987, the Congress provided in a Supplemental Appropriation (P.L. 100-71) $1,000,000 to the NCNR to be evenly divided with the Division of Nursing, Health Resources and Services Administration (HRSA), to address the nursing shortage issue. The $500,000 allocation to the NCNR plus resources from the NCNR's FY 1987 appropriation were used to support seven research project grants, sixteen Individual National Research Service Awards, one Institutional National Research Service Award, and one career development award related to nursing resources and patient care delivery. Projects were funded to study the factors that influence nurse retention in neonatal intensive care units; the effectiveness of special care units for certain patient populations that have difficult and complex nursing care problems and the effect of the units on caregiver satisfaction; the relationship between nursing work site characteristics and drug use related to stress; and the efficacy of a computerized decision support system for clinical nursing practice that would increase the quality of, and decrease the time required for, effective patient care planning.

The NCNR has also sponsored a two day national interdisciplinary conference that brought together leading nurse scientists, health administrators, economists, and representatives of other NIH components and other Federal agencies, including the Chairman and Executive Director of the Commission on Nursing established by the Secretary, Department of Health and Human

Services. The invitees discussed and deliberated on what past studies in this area have revealed, what has and has not been implemented, and what still requires further study. The conference outcomes will be reflected in a report that should be of value not only to the research mission of the NCNR, but to other government and nongovernment organizations as well. It is anticipated that some of the findings of the conference will appropriately be implemented by the Division of Nursing, HRSA, through its authority in title VIII to support demonstration projects and nursing education programs targeted for special purposes. The conference was planned by the NCNR and cosponsored by the Division of Nursing, which held a separate conference on the educational and practice aspects of the issue, cosponsored by the NCNR.

In addition, the NCNR has published a Program Announcement that communicates to the nursing research community the NCNR's interest in supporting research that will result in strategies and interventions to improve the availability and retention of registered nurses to provide quality patient care in a variety of clinical settings. Some topics that could be investigated are availability and retention of nurses in selected high stress clinical areas, such as patients with HIV infections, care of the elderly or care of the premature newborn, factors that affect nurses' decisions to remain in or leave nursing practice and the effect of multiple employment options, allocation of nursing resources, staffing requirements, and costs.

The NCNR and the Division of Nursing have just initiated a collaborative effort to support research and demonstration projects on innovative practice models for restructuring nursing resource management and delivery of patient care methods. This collaboration will use the expertise and authorities of both agencies. The purpose of the effort is to develop, implement and study replicable nursing care delivery models in hospitals to test approaches for increasing available nursing resources and influencing quality care, including consideration of cost and benefit.

Question

There is a strong feeling in the academic community that there is an urgent need for funding to renovate existing research facilities and to construct new ones. Is there a facilities problem for nursing research?

Answer

The last time construction dollars were appropriated for nursing purposes was in 1978, authorized under the Nurse Training Act, and administered by the Division of Nursing, HRSA. This construction authority was focused on educational activities; it did not include research facilities. The American Association of Colleges of Nursing (AACN) is conducting a survey on nursing research facility needs that will provide comparable information to the NSF survey for the NIH.

Senator MIKULSKI. Thank you very much, Doctor, for that very brisk and fast-paced testimony. All those little beepers you hear mean that the cloture vote is underway. We expect Senator Weicker to return momentarily, in which we are going to then ask Dr. Hinshaw to make her presentation.

However, in the interest, again, of expediting, I have some questions related to the need for an NIH building, which I think came up at last year's hearing, and some questions related to some research areas that I am going to ask my staff to pose so that we could move on the record.

Then, when I come back, I want to pursue specifically myself the concerns related to work force, and particularly this issue of recruitment, attraction, and retention.

Before I leave to go to the vote, I think that this is a very special hearing not only because of the excellent presentation you are making, but I know later on today Senator Harkin will be chairing the component in which we will be taking testimony on whether or not we should establish a National Institute for the Deaf or Hearing Impaired. And I just would like to comment that the recent activity at Gallaudet College has been in the great tradition of a democratic country. And I think for once, the deaf community spoke up, and we had to learn how to listen, and we had to learn to listen in a new way. And the processes of this hearing that we will undergo with Panel III show that there should be no barriers to participation in our society.

So we look forward to receiving testimony in any way people want to communicate to us, and we look forward to that exchange.

So with that, I am going to ask Ms. Vincent to take the Chair.

Ms. VINCENT. Dr. Wyngaarden, I understand that NIH is interested in a new building on the Bethesda campus to consolidate the personnel from four off-campus locations. The proposal, as the Senator understands it, would be to construct the building under lease-purchase authority at an annual savings of $1 to $2 million, less than the current rental payment for the four off-campus sites.

We do not currently have the necessary authority for this building included in the NIH reauthorization bill. I wonder, for the benefit of the Committee and the hearing record, could you please detail the benefits of this proposed building consolidation program?

Dr. WYNGAARDEN. Yes, I would be happy to speak to that.

As you indicate, we have a considerable number of NIH personnel located off-campus in rental space—four major buildings, about 2,900 personnel, located in Bethesda on River Road in part and also in locations in the Rockville area.

These individuals include some scientists, chiefly those concerned with the management of the Extramural Grants Program. There are major disadvantages in having them located so far away from the center of activities on the NIH campus. For example, these are people with science backgrounds who are now science administrators who must maintain their currency in science in the areas in which they are managing programs. To do that requires that they interact with scientists, that they attend seminars in their field, that they have free access to the libraries—and that is very difficult when they are located several miles away.

If we could relocate them on the campus, many of those problems, I think, would be reduced or eliminated. We do have the space for the building. We have also had a preliminary design done of it, one that meets our specifications and would provide underground parking for the number of people concerned. This building would bring these individuals into contact with their professional colleagues on the NIH campus.

As you indicate, we have looked at the relative cost of new construction versus lease-purchase construction versus the continued rental programs, and we believe we can demonstrate considerable savings, perhaps over 20 years as much as $100 million, and we will then own the building.

Ms. VINCENT. What would your timetable be for this building?

Dr. WYNGAARDEN. It would be another year or two if the authorization were available, I think, to complete the design of it and begin construction and, given the size of the building, I suspect it would be a two, two and a half-year construction period.

Ms. VINCENT. And is this the same building that was talked about last year with regard to AIDS and creating a new AIDS facility?

Dr. WYNGAARDEN. No. This would include some of the extramural managers of the AIDS Program, but it is not specifically an AIDS building.

Ms. VINCENT. Let me turn now to the issue of Alzheimer's. Can you quickly tell us the status of some of the promising research underway on Alzheimer's?

Dr. WYNGAARDEN. There has been a considerable advance in the understanding of Alzheimer's disease in recent years. For example, we now know that Alzheimer's is a specific disease. A few years ago it was considered perhaps an inevitable consequence of aging. But it has a specific pathology. Certain, exact locations of the brain are involved in Alzheimer's disease. There are characteristic chemical changes associated with this disease. There are neurofibrillatory tangles and amyloid deposits which are quite characteristic of this disease.

The fact that it can be characterized as a specific disease suggests that it may have one or more specific causes and as we learn more about those, the opportunities for prevention or interruption of the progress would be considerably enhanced.

On the genetic front, we know that there is an Alzheimer's susceptibility gene. In somewhere between 4 and 10 percent of families, there is a strong familial tendency. And in some of those families with a high incidence of Alzheimer's, it has been determined that this Alzheimer's susceptibility gene resides on Chromosome 21.

We also know that the amyloid protein that accumulates in Alzheimer's disease and many other diseases is determined by a gene on Chromosome 21. We don't know whether those are the same or different genes.

Finally, there are Alzheimer-like changes in Down's Syndrome, and Down's Syndrome is also determined by chromosomal alterations on Chromosome 21.

So you can see that the scientific plot thickens, and we desperately need to know more about what functions these various areas on Chromosome 21 are controlling.

On the other side, there have been advances in procedures for early autopsy that have enabled scientists to determine changes on brain that has not undergone post mortem autolytic changes, as they are called; that is a very substantial advance that may enable us to learn more about the pathology of this disease. And then, the finding that certain specific chemical changes are characteristic of the areas involved pathologically—for example, low levels of acetylcholine have led to the use of cholinesterase inhibitors, drug inhibitors that will block the enzyme that normally breaks down the acetylcholine that is there. And one of these, called THA, or tetrahydro-amino-acridine, is the subject of a very large clinical trial that was started some time ago, at rather high doses of that compound, and there were some liver enzyme changes in patients receiving that compound so the trial was interrupted and then later reintroduced at lower dose levels, and it is now under way at several centers at lower dose levels.

This trial was initiated because a physician in California had made some observations suggesting that the compound might have a beneficial effect on patients with Alzheimer's disease, and that is now the subject of a trial.

Ms. VINCENT. Well, you anticipated the Senator's next question, which was how the THA trials are going. It sounds like there is a great deal going on in the area of Alzheimer's, but the Senator is concerned that we are not doing enough for Alzheimer's and other severe forms of dementia. As our population ages, the problem is only going to get worse.

She would like to request that you submit to her and to Senator Chiles, who chairs the appropriate subcommittee on appropriations, your professional judgment budget for Alzheimer's. The Senator is particularly concerned about help to families with Alzheimer's victims and hopes that the professional judgment budget will include research on how to better manage Alzheimer's cases and to better treat Alzheimer's patients.

Dr. WYNGAARDEN. We would be happy to do that. I might just mention that Alzheimer's research is very active in three of our major institutes. The Aging Institute has the largest program, but the National Institute of Neurological and Communicative Disorders and Stroke has a very large program, and also the Mental Health Institute. And our NIH share of Alzheimer's research amounts to nearly $90 million in 1988.

[Information supplied follows:]

NATIONAL INSTITUTES OF HEALTH
FY 1989 Professional Judgement Budget for Alzheimer's Disease

National Institute on Aging

The National Institute on Aging's FY 1989 professional judgement budget for Alzheimer's disease is $102, 467,000, an increase of $43,800,000 over the 1989 estimate of $58,667,000. The increase will provide funding for the following research initiatives, which will enhance our knowledge of the diagnosis, cause and treatment of Alzheimer's disease (AD) and of the care of Alzheimer's patients. Offsets have not been identified to finance such an increase and, thus adhere to the principles of the Congressional Bipartisan Budget Agreement.

The Alzheimer's Disease Research Centers (ADRCs) have become an exceptional vehicle for the rapid exchange and transfer of scientific information and for facilitating collaboration between centers. An additional four centers will serve to expand the clinical and research base on AD; open opportunities for recruitment of new collaborative research initiatives tied to the larger ADRC program; increase the national effort to provide more sophisticated diagnostic procedures to wider segments of the U.S. population; and provide resources for more specialized training of health care providers. An additional $4,500,000 is needed for these new centers.

Title IX, section 931, of P.L. 99-660 authorizes the NIA Director to make awards to distinguished senior investigators who have made significant contributions to biomedical research related to AD and other dementias. This program is intended to strengthen the capabilities of established senior investigators who have distinguished records in biomedical research on AD and allow recipients time to devote to research and the research development of outstanding junior biomedical investigators who are interested in working on AD research. To expand this program, five new awards are needed for a total cost of $5,000,000.

NIA has established seven AD patient registries to develop and test various models and methods needed to establish a large area or national Alzheimer's disease registry program. Increased funding will allow the expansion of current efforts to develop links between academic researchers and State government activities and the establishment of sentinel registries in special populations prior to the development of a national registry. An increase of $4,300,000 is needed for this effort.

Treatment of AD is an important priority for NIA. As a first step in this direction, NIA funded a multi-center clinical trial to test the safety and efficacy of THA. Should this be confirmed, it would be a palliative treatment only, since the underlying process of degeneration of cholinergic neurons is not altered by the anticholinesterase activity of THA. AD is not restricted to deficits of the cholinergic system but also of other neuronal transmitters. Thus new therapeutic strategies are being designed which accommodate the diverse neurochemical deficits seen in the AD population by restoring the functional integrity of a number of affected systems. The possibility of even a short extension of normal and productive life of both the AD patient and his/her family is very important. To test such new drugs, $4,100,000 is needed.

The ADRCs have made efforts to train and provide research experiences in basic and clinical research for doctorally prepared junior investigators. The efforts must be broadened, however, to include social workers, nurses, home health aides, homemakers, and those people with primary responsibility for care. Additionally, there is a major national shortage of neuropathologists trained in the molecular pathology of AD and related disorders. To enhance the overall training effort in AD, $1,600,000 is needed.

In January 1987, NIA began formal planning activities to establish an Alzheimer's Disease Education Center. A primary component of the Centers is an information and education materials development activity in response to a market research study conducted last year. We have learned that there are many local community organizations that want to provide more information on AD but do not have the written materials and brochures or the resources to develop them. Thus, NIA can make a significant contribution and can significantly extend its usual distribution channels by developing information materials for use and distribution by local organizations. NIA has budgeted funds to initiate the Center but to meet the public need for information on diagnosis, behavioral management and new therapies requires a markedly expanded effort. Therefore, an additional $1,200,000 is required.

In addition to the above, there are five areas in which NIA would like to expand its research efforts.

- Shared Research (tissue bank) Facility: While major advances are being made in the genetics of AD, the numbers of families identified and of samples banked for investigators is insufficient to permit further identification, isolation and characterization of the affected gene(s). The establishment of such a center requires $1,500,000.

- Cause of Alzheimer's Disease: Important advances in AD are expected in several areas. Two particularly exciting areas are in the effects of infections and of toxins on the aging nervous system. Recent research findings, which are going to reawaken research interest in the possible role these agents play in the genesis of AD, need to be expanded to determine the extent to which they may predispose the aging nervous system to increased risk of infections. An increase of $8,200,000 is needed to take advantage of existing opportunities for determining the cause of AD.

- Developing Better Diagnostic Techniques: Important research findings by several NIA grantees indicate the potential for biochemical diagnostic tests for AD based upon the detection of specific biological markers. Most of these can only be performed on postmortem tissues. Thus there is a need to search for antemortem diagnostic biochemical markers for AD, especially for the early stages of the disease when potential interventions would be most effective. An additional $6,300,000 is needed for these studies.

- o Burden of Care: Most Alzheimer's disease patients receive care from their family members, friends and neighbors. Research must be expanded on: the social and behavioral aspects of care of AD patients, including the impact of AD on families, support networks and formal health care system; help-seeking behavior and social and behavioral treatment responses; social, behavioral, technological, and environmental interventions in caring for AD patients and reducing caregiving burdens; and forecasting long-term care demands for AD care and the economic implications. To expand these research efforts, $2,400,000 is needed.

- o Cross-Cultural Study: Differences in incidence rates among countries, in distinct subpopulations or by acquired characteristics may yield clues about risk factors which might then lead to new hypotheses about etiology. To undertake such studies, $3,700,000 is required.

NIA's intramural research program on Alzheimer's disease is conducting drug treatment and pharmacokinetic studies of AD. Such approaches will help us learn more about the structural and functional bases for AD and how these measures of the disease relate to one another. To expand this intramural effort, four additional FTEs and two additional beds in the Clinical Center are vital. The additional cost is $1,000,000.

National Institute of Neurological and Communicative Disorders and Stroke

The 1989 Professional Judgement estimate for Alzheimer's disease is $28,730,000, an increase of $6,900,000 over the 1989 estimate of $21,830,000. The increase would provide for the following research activities with the goal of better management and treatment of Alzheimer's disease patients. I would note, however, that lower priority offsets have not been identified to support the increase, yet adhere to the principles of the Congressionally approach Bipartisan Budget Agreement.

Expand molecular genetics studies to further refine the knowledge of amyloid plaque and its gene as it relates to Alzheimer's disease. ($500,000)

Expansion of the pedigrees for the identification of the Alzheimer's gene. Further development of recombinant DNA techniques to facilitate the identification of genetic marker for Alzheimer's disease. ($500,000)

Studies will focus on the biochemical mechanisms underlying the molecular genetics of Alzheimer's, including abnormal neuronal development, or specific vulnerability of the nervous system to environmental factors. ($1,000,000)

Positron emission tomography (PET) and magnetic resonance imaging (MRI) will be used to follow the course of Alzheimer's disease from the earliest changes in presymptomatic subjects to allow for early diagnosis and eventually intervention. ($1,500,000)

The genetic factors involved in the occurrence and pathogenesis of Alzheimer's disease will continue to be explored. A genetic marker for the disease is being sought by genetic linkage studies in large families having many members which have developed the dementia. ($600,000)

Monoclonal antibody techniques will be used to study differences between normal and Alzheimer's disease brain cells with respect to neurotransmitters, receptor, and metabolic regulatory molecules; intracellular structural and transport proteins; and molecular genetic process. ($1,900,000)

Four additional FTEs for intramural research to expand and further explore genetic and other factors in Alzheimer's disease. ($1,000,000)

NICHD

The NICHD's professional judgment level for Alzheimer's disease in FY 1988 is $900,000. The $250,000 increase over the FY 1989 President's Budget would eliminate the negotiated reductions in research project grants as well as allow for additional program projects through planned expansion of the research centers program, which includes two new mental retardation centers. Offsets to support this increase have not been identified.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

ALZHEIMER'S DISEASE

(Dollars in Thousands)

| | 1981 Actual | 1982 Actual | 1983 Actual | 1984 Actual | 1985 Actual | 1986 Actual | 1987 Actual | 1988 Estimate | 1989 Estimate | Increment | 1989 Profess. Judgement Level |
|---|---|---|---|---|---|---|---|---|---|---|---|
| NHLBI | --- | --- | --- | $90 | $88 | $44 | --- | --- | --- | --- | --- |
| NINCDS | $5,427 | $6,243 | $8,678 | 11,700 | 12,826 | 15,028 | $18,611 | $19,900 | $21,830 | $6,900 | $28,730 |
| NIAID | 1,394 | 1,256 | 1,041 | 1,336 | 1,211 | 1,184 | 1,446 | 1,493 | 1,569 | 498 | 2,067 |
| NICHD | --- | --- | --- | --- | --- | 91 | 583 | 600 | 650 | 250 | 900 |
| NEI | --- | --- | --- | --- | --- | 490 | 62 | 63 | --- | --- | --- |
| NIEHS | --- | --- | --- | --- | --- | 312 | 327 | 472 | 489 | --- | 489 |
| NIA | 5,196 | 8,054 | 11,848 | 21,456 | 28,830 | 32,938 | 42,038 | 54,956 | 58,667 | 43,800 | 102,467 |
| DRR | --- | --- | 604 | 709 | 1,034 | 1,720 | 2,010 | 2,183 | 2,004 | 396 | 2,400 |
| Total, NIH | 12,017 | 15,553 | 22,171 | 35,291 | 43,989 | 51,807 | 65,077 | 79,667 | 85,209 | 51,844 | 137,053 |

The NIH currently estimates spending 85.2 million in 1989 for Alzheimer's disease. The professional judgement level would be $137.1 million, an increase of $51.8 or 61 percent.

Of this additional amount approximately $16.9 million, one third of the increase, would be devoted to the exploration of phamacological treatment of the disease and develoment of management strategies for family and professional health care givers. The balance of the amount would be targeted for the expansion and exporation of new research methodologies, expansion of patient registry, and creation of 4 new Alzheimer's Diease Research Centers.

Ms. VINCENT. Let me turn quickly to the AIDS issue. One thing that concerns the Senator about the response to the AIDS problem is that we have seen more than a ninefold increase in AIDS funding since 1985, while the personnel devoted to AIDS at NIH has grown only threefold.

Do you have enough people to manage the AIDS problem?

Dr. WYNGAARDEN. We have received additional FTE allocations for the AIDS program. The point I would stress is that that is an ongoing program, and estimates that we prepare at one time may not be valid at a later date.

We have identified just recently the need for a considerably increased number of personnel in the AIDS program, and we have submitted that request to the Department.

Ms. VINCENT. This is of particular concern because NIH is under directive from the Appropriations Committee to make AIDS-related grants, contracts, and cooperative agreements within six months. Can you meet this directive with the level of personnel you have?

Dr. WYNGAARDEN. We are attempting to do that. We have determined that the applications that are received February 1 and March 1 will be made within six months.

In order to initiate that accelerated review process, we have had to borrow about 40 individuals from within NIH and within ADAMHA to work on this accelerated program, and we will need to replace those with an additional 40 people in order to keep that program going.

Ms. VINCENT. Let me turn briefly to extramural facilities construction.

Some Members of Congress are dubious about whether real need exists to spend millions of dollars on the renovation of research facilities. They are also doubtful that we need more research space, given the rapid rate of progress in medical research in recent years.

What do you have to say to them?

Dr. WYNGAARDEN. There have been over the years a number of statements on the need for additional research facilities in several categories.

There is a need for upgrading the existing facilities. There is need for upgrading the animal facilities and for building new ones. Many campuses have need for new facilities to handle toxic waste substances. And there is need for new laboratory facilities in new areas.

At the request of the Congress, we convened a committee in early February. As I mentioned, that committee met; it received testimony from a number of professional groups; and it wrote a very good report, which is in draft and being prepared for final publication now.

That committee identified a very large need. They recommended a ten-year program. The first two years would be in the nature of a pilot program and would be one in which, if approved, $100 and then $200 million would be provided for renovation and enlargement of buildings, but not for construction of new freestanding buildings. During that time, the longer-range program would be sharpened up. They then recommended an additional eight years, funded at $350 to $500 million per year.

They made a number of additional recommendations that would address both the issue of equity financing, such as 50-50 sharing and debt-financing, such as accelerated depreciation on buildings built with non-Federal funds, accelerated depreciation of instruments. And I think two witnesses who will appear later today would be prepared to speak to the details of the report that they are now putting in final form.

Ms. VINCENT. Senator Mikulski has returned.

Senator MIKULSKI. We have one question for the record related to extramural facility construction, and I am going to ask them, but then turn them over to your able staff for answer, one of which is: Will the facilities construction authority which would be established by NIH authorization be adequate for your needs? Many have expressed concern about the "have-not" institutions and whether they will benefit at all from a program like this. We will raise some others.

One last question on funding of specific research to you, and then we want to go on to Dr. Hinshaw to come back to the workforce questions.

This goes to AIDS funding. The Administration's 1989 request for NIH AIDS research funding is $588 million, which is actually more than the original NIH request, $565 million. On an overall basis, I understand NIH requested $8.4 billion to fund the various professional judgment budgets.

Let me get to the question. Although this was reduced by $7 billion, is it accurate to say, Doctor, that AIDS is the only area that was increased by the Administration through the 1989 budget process, and is it accurate to say that AIDS is the only research area at NIH that is fully funded at the professional judgment level?

Dr. WYNGAARDEN. Yes, I think those are both accurate statements—at the professional judgment level, and it is really at the NIH professional judgment level. We have a very detailed internal process for evaluating the submissions by the individual institutes, and sometimes there is overlap in what one or another institute proposes. So the AIDS Advisory Committee, headed by Dr. Fauci, and I go over these line-by-line, so that what is submitted to the Department is a professional judgment budget that we think we can defend. That request has been fully funded by the Department, by OMB, and in the President's budget request the last couple of years.

Senator MIKULSKI. Thank you very much. And we thank you for accepting this kind of unorthodox way of holding the hearing.

Dr. Hinshaw, would you please proceed? I understand you want to brief us on the national nursing shortage and some ideas that the National Center for Nursing Research has.

Would you please proceed?

Dr. HINSHAW. Thank you, Senator.

It is a privilege for me to address this Committee as the Director of the National Center for Nursing Research. The nursing research community is proud to be represented by the Center as the newest part of the NIH. I am pleased to report on the Center's establishment, our research programs and plans for the future, including research on the nursing shortage.

The Health Research Extension Act of 1987 authorized the National Center for Nursing Research. Following formal establishment of the Center in 1986, necessary first steps included a number of activities, varying from hiring staff to augment the nine persons transferred from the Division of Nursing at HRSA to making initial research project grants and research training awards as a component of NIH.

These steps were accomplished not without difficulty, but relatively smoothly, thanks to the diligent efforts of our early core staff, and particularly Dr. Doris Merritt, who served as NCNR's acting director, and with the generous assistance of the NIH community.

In two years, the Center has exhibited vigorous growth. Our programs and staff have increased, and our budget has grown by 41 percent, to a total of $23.3 million in fiscal year 1988.

This year, we plan to award 128 research project grants and support 191 research trainees, compared to 100 research project grants and 165 research trainees in 1986. We are programmatically and administratively sound and fully functional.

The ultimate purpose of nursing research is to generate and test knowledge that will enable health care providers including nurses to give better care. The client and the family, as they respond to the promotion of health and the treatment of illness, are the foci of nursing research. To this end, the Center supports basic and clinical research and research training through research project grants, training grants, and career development awards.

Scientific programs include acute and chronic illness, health promotion and disease prevention, and nursing systems.

Let me provide some examples of scientific studies which we are supporting and from which important information for nursing will evolve. One area concerns the adequacy of patients' oxygenation during routine nursing care. A consortium of four projects is studying levels of blood oxygen saturation during turning, positioning, backrubbing, and endotracheal suctioning. Findings should provide a basis for establishing strategies or procedures that minimize a patient's oxygen loss during nursing care.

Another area of promising research deals with urinary incontinence, a major health problem associated with aging and long-term care. We are supporting studies on behavioral interventions including prompted voiding, biofeedback, pelvic muscle exercise, and bladder control. The delivery of nursing care could be enhanced with the result of these investigations.

A critical area of health being addressed by nurse researchers concerns the impact of family functioning when infants are born with structural or metabolic defects and very low-birth weights.

Another research area relates to the safety and cost-effectiveness of follow-up home care by nurse specialists for low-birth weight infants who are discharged early from the hospital.

The NCNR has undertaken a number of initiatives addressing society's and the profession's concern with the nursing shortage. In fiscal year 1987, a supplemental appropriation provided $1 million to the NCNR for a joint endeavor with the Division of Nursing at the Health Resources and Services Administration to address this issue. These funds, and other NCNR dollars, provided support for

25 research project grants, fellowships, and career development awards related to nursing resources and patient care delivery. These include, for example, studies of nurse retention in intensive care units, and studies on drug use, stress and job performance among nurses.

We have also published a program announcement in the *NIH Guide for Grants and Contracts,* expressing interest in applications focused on strategies that can be used to recruit and retain registered nurses in patient care agencies, especially hospitals.

We have collaborated with the Division of Nursing in cosponsoring of several conferences on nursing resources and the delivery of patient care.

In June of 1987 the Center, with the vigorous participation of the nursing scientific community and its Advisory Council, began a two-year-long planning process to define a National Nursing Research Agenda. The objectives are to provide a structure for selecting scientific opportunities, identifying research priorities, and to give direction and momentum to research within the nursing discipline.

We are cognizant of the need to increase the number of predoctoral and postdoctoral research fellows and trainees consistent with the recommendations of the National Academy of Sciences Committee on National Needs for Biomedical and Behavioral Research Personnel. We are providing individual and institutional research training opportunities for both predoctoral and postdoctoral fellows, have initiated career development awards for nurse scientists, are emphasizing postdoctoral opportunities in established NIH-supported research centers, and have begun to define a logical research training and career development trajectory for nurse investigators.

Madam Chairman, the National Center for Nursing Research has, in its relatively brief two-year existence, established a strong program of research and research training. We will build on this foundation to generate the new knowledge nurses will need in the future to provide quality care to patients nationwide.

I would be pleased to answer any questions you may have.

[The prepared statement of Dr. Hinshaw follows:]

STATEMENT

BY

ADA SUE HINSHAW, PhD, RN

DIRECTOR
NATIONAL CENTER FOR NURSING RESEARCH
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

U.S. SENATE

MARCH 29, 1988

Madam Chairwoman and Members of the Committee:

It is a privilege for me to address this subcommittee as the Director of the National Center for Nursing Research. The nursing research community is proud to be represented by the Center as the newest part of the National Institutes of Health. I am pleased to report on the Center's establishment, our research programs, and plans for the future.

Establishment of the NCNR

The Health Research Extension Act of 1985 (PL 99-158) authorized the National Center for Nursing Research as part of the NIH. Following formal establishment of the Center in April 1986, necessary first steps included:

- o hiring staff to augment the nine persons transferred from HRSA's Division of Nursing,
- o locating space to house staff members,
- o establishing a National Advisory Council,
- o developing peer review groups and processes, and
- o making initial research project grant and research training awards as a component of NIH.

These steps were accomplished not without difficulty, but relatively smoothly, thanks to the diligent efforts of our early core staff -- particularly Dr. Doris Merritt who served as NCNR's Acting Director until my appointment in June 1987 -- and the generous assistance from the NIH community.

In two years, the Center has exhibited vigorous growth. Our staffing has increased to 28 FTEs and our budget has grown by 41 percent to a total of $23.3 million in fiscal year 1988. This year, we plan to award 128 research project grants and support 191 research trainees, compared to 100 research project grants and 165 research trainees in fiscal year 1986. We are programmatically and administratively sound and fully functional.

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Research Programs

The ultimate purpose of nursing research is to generate and test knowledge that will enable health care providers including nurses to give better care. The client and the family, as they respond to the promotion of health and the treatment of illness, are the foci of nursing research. To this end, the Center supports basic and clinical research and research training in nursing science through research project grants, research training grants, and career development awards. Scientific program areas include acute and chronic illness, health promotion and disease prevention, and nursing systems.

Let me provide some examples of scientific study which we are supporting and from which important information for nursing will evolve. One area concerns the adequacy of patients' oxygenation during routine nursing care. A consortium of four projects is studying levels of blood oxygen saturation during turning, positioning, backrubbing, and endotracheal suctioning. Findings should provide a basis for establishing procedures that minimize a patient's oxygen loss during nursing care.

Another area of promising research deals with urinary incontinence, a major health problem associated with aging and long-term care. We are supporting studies on behavioral interventions including prompted voiding, biofeedback, pelvic muscle exercise, and bladder control. The delivery of nursing care could be enhanced as a result of these investigations.

A critical area of health being addressed by nurse researchers concerns the impact of family functioning when infants are born with structural or metabolic defects and very low birth weights. Another research area relates to the safety and cost effectiveness of follow-up home care by nurse specialists for low birth weight infants who were discharged early from the hospital.

Nursing Shortage

NCNR has undertaken a number of initiatives addressing society's and the profession's concern with the nursing shortage. In fiscal year 1987, a supplemental appropriation provided $1 million to the NCNR for a joint endeavor with the Division of Nursing, HRSA, to address the shortage of nurses and to support hospital-based clinical research projects. These funds, and other NCNR dollars, provided support for 25 research project grants, fellowships, and career development awards related to nursing resources and patient care delivery. These include, for example, studies of nurse retention in intensive care units, and studies of drug use, stress, and job performance among nurses. We have also published a program announcement in the NIH Guide for Grants and Contracts expressing interest in applications focused on strategies that can be used to recruit and retain registered nurses in patient care agencies, especially hospitals.

NCNR is collaborating with the Division of Nursing in co-sponsorship of several conferences. Both NCNR and the Division of Nursing have continued their research and demonstration endeavors in nursing resources and the delivery of patient care consistent with their respective authorities.

Plans for the Future

In June 1987 the Center, with the vigorous participation of the nursing scientific community and the NCNR Advisory Council, began a two-year long planning process to define a National Nursing Research Agenda. The objectives of the Agenda are to provide a structure for selecting scientific opportunities, identifying research priorities, defining initiatives to promote greater depth in developing a knowledge base for nursing practice, and to give direction and momentum to research within the nursing discipline. When completed,

the National Nursing Research Agenda will serve as a blueprint to guide the development of our research programs in the years to come.

The NCNR is cognizant of the need to increase the number of predoctoral and postdoctoral research trainees consistent with the recommendations of the National Academy of Sciences Committee on National Needs for Biomedical and Behavioral Research Personnel. We are providing institutional research training opportunities for both predoctoral and postdoctoral trainees, have initiated career development awards for nurse scientists, are emphasizing postdoctoral training opportunities in established NIH-supported research centers, and have begun to define a logical research training and career development trajectory for nurse investigators. These plans should assist nurse investigators in obtaining initial and periodic research training and career development support through the appropriate NIH award mechanism.

Madam Chairwoman, the National Center for Nursing Research has, in its relatively brief two-year existence, established a strong program of research and research training. We plan to build on this foundation to generate the new knowledge nurses will need in the future to provide high quality care to patients nationwide. I would be pleased to answer any questions you may have.

Senator MIKULSKI. Well, thank you very much, Dr. Hinshaw. I do have some questions related to you.

I think all of us are very much concerned about the national nursing shortage. Also, it is the Chair's understanding that there is a study group in the Office of the Secretary on the nursing shortage. I believe Dr. Lillian Gibbons is the executive director.

Dr. HINSHAW. That's correct.

Senator MIKULSKI. How closely are you coordinating with that, and do you have any preliminary findings that you could share with the Committee?

Dr. HINSHAW. The Commission on Nursing and the personnel staffing that Commission are working closely with the Director of the Division of Nursing in HRSA as well as with me at the National Center for Nursing Research.

Senator MIKULSKI. Excuse me. When you say "HRSA"——

Dr. HINSHAW. Health Resources and Services Administration.

The reason I make that distinction is that the Division of Nursing is really the entity that has the authorization to deal with manpower and educational issues. The National Center focuses on the research aspects of these issues by supporting studies of various aspects of the nursing shortage dilemma.

We are working closely with the Commission by providing the information that we are gaining from our research, have gained in the past from other research studies, and will gain from those projects that we have just funded. Those that we have just funded obviously will take a while to come to fruition.

But our involvement, primarily with the Commission, has been through the sharing of information and planning for the issues that need to be confronted.

Senator MIKULSKI. Doctor, would it be safe to say that one of the reasons that there is a nursing shortage is that nurses are not adequately paid and not adequately respected?

Dr. HINSHAW. I think that as the Commission on Nursing hears testimony from different individuals and witnesses, it is becoming clear that there are two aspects to this issue. One is the lack of pay. The other is the lack of ability to control practice, to develop autonomy within their professional practice, and to function in environments which will allow for and enhance their professional practice. And therefore, a short-term answer would seem to be pay, from what these witnesses are suggesting, but the long-term answers will require confronting these environmental issues regarding long-term professional practice.

Senator MIKULSKI. Doctor, as part of the research that is going on, is one examining the difference in scope between what a two-year nurse can do, a two-year community college R.N. to the bachelor's degree in nursing, to those who are post-baccalaureate and trained in more solo practice approaches like nurse practitioner? In other words, does everybody, to be a good nurse, need a bachelor's degree, or is it certain types of nursing need a bachelor's degree, and we need to start getting that kind of clarified?

Dr. HINSHAW. That is one of the areas that is being looked into with the Division of Nursing's demonstration projects and demonstration authority. I cannot answer at this time regarding what those findings are showing.

There is concern in the profession about what level of education is required for adequately providing patients with certain types of care and necessary levels of acuity.

Senator MIKULSKI. Well, yes. We look forward to that. We would hope that this is a focus of the research that goes on. For example, when one looks at straight bedside care in a nursing home, that requires one type of care—skilled, compassionate, dedicated, but old-fashioned as we would know it, the Nightingale/Clara Barton approach.

Dr. HINSHAW. Yes.

Senator MIKULSKI. Then, there is the nursing supervisor in that same nursing home, who might be the only professionally trained person over a variety of staff. We would understand that would require a higher level of education, more administrative skills and so on, all the way up, then, to nurse practitioners working in schools and really rural communities, who really have autonomous practices.

We feel—at least I, speaking as a member of the Committee—feel that we would need to look at that to be sure that, when we talk about a nursing shortage, what are we talking about.

Dr. HINSHAW. I think the individuals in the profession would certainly agree with you.

Senator MIKULSKI. Thank you, and we thank you for looking at that.

Dr. Rosenberg—and I know Dr. Wyngaarden has raised the work force issue—I understand you are a star; that you have had all kinds of offers from the private sector to do research or a variety of other things.

Could you tell us a little bit about yourself? I am a social worker, so I like the case study method rather than memos. In fact, I'd like to get this Committee making more home visits and less hearings like this.

Dr. ROSENBERG. I am a surgeon, the Chief of Surgery at the National Cancer Institute. I went to medical school at Johns Hopkins, did my residency at one of the Harvard teaching hospitals, the Peter Bent Brigham Hospital; and after finishing that residency, came to the NIH as Chief of the Surgery Branch.

In that capacity, I am responsible for surgery at the Clinical Center, that is, the NIH's major hospital. It is a 520-bed hospital that takes care of the patients who are admitted as part of research protocols that attempt to develop improved methods of treatment of patients with the wide variety of diseases cared for at the NIH.

As a surgeon responsible for maintaining a staff responsible for surgical care for this hospital, I certainly confront the problems of recruitment and retention of surgeons on Government salaries on almost a daily basis, and it is a major problem. I would like to put that in the context of what I think is the reason that people come to work at the NIH, not only at clinical research levels but at scientific levels.

It is truly a remarkable institution. As I have travelled through other academic institutions, there is no place in the world like the National Institutes of Health. Its total mandate, its total reason for

existence, is to make progress in defining better ways to manage patients who are sick.

We have no primary patient care responsibility to our community. We have no emergency ward that handles trauma. Physicians and scientists who come to the NIH come there because they are dedicated to making progress in treating, curing and preventing disease. And in that sense, the facilities are remarkable.

It is an institution that has outstanding research laboratories just 20 yards from major research clinical wards——

Senator MIKULSKI. We know why NIH is good. Is that why you are there?

Dr. ROSENBERG. That's why I'm there, and that's why people come to the NIH. People stay at the NIH despite the fact that the salaries for people who work at the NIH are often one-third to one-quarter what they would be earning at comparable academic institutions.

If, for example, we look at some numbers, the American Association of Medical Colleges tabulates each year salaries that surgeons, for example, receive at our country's medical schools. The median salary for a chief of general surgery at a medical school in the United States is $214,000 a year. For a full professor of surgery at medical schools in this country, the median salary is $174,000 a year.

The maximum salary that I can offer a surgeon beginning at the NIH is $56,000, and the maximum salary of any surgeon working at the NIH is about $80,000. Now, that's less than one-third of the salary at many institutions.

So I preface my remarks about the outstanding nature of the NIH to try to place in context the reason that people come to the institution.

I think the dedication of the workers at the NIH, the reason that they stay despite the salary differentials with academic institutions, in part explains why the achievements of NIH scientists are so outstanding. But at some level, one runs into practical difficulties.

You asked for case studies. I have three daughters, one of whom is 16. We are starting to look at colleges for her. That's not easy, compared to the kinds of situations that I might confront with any one of a dozen offers I have had in the past year.

So in that context I would certainly think that looking at the salary structure for clinical scientists at the National Institutes of Health is something very much worth examining.

Senator MIKULSKI. Well, this then goes exactly to my work force question—and thank you for sharing that personally, as a dad. I think we all know that the cost of college now—at a modest college; we are not even talking about a high-priced, tony school—that is really the cost of what a home might have cost ten years ago.

But in order to attract or retain people, do you think some type of—well, let me back up. Very often, the cost of education, whether it is medical school, nursing school, post-college, post-baccalaureate, the nurse practitioner, the physician, the Ph.D. in biochemistry, they incur an enormous amount of student debt and in fact feel in some ways that they are already an indentured class in order to obtain that education.

Do you think that one technique for the attraction of government service should be some type of debt reduction; that if you come to work at NIH, we would forgive a certain percentage of your student loan?

What would you think about that, Dr. Rosenberg—and Dr. Wyngaarden, I'd like your comment as well.

Dr. ROSENBERG. There is no question that many of the clinicians that we attempt to attract at the NIH, a unique group of clinicians who have experience in research as well as outstanding clinical care, come to their first position following their clinical training having incurred substantial debt in college, and in medical school. The average surgical residence in this country is six years beyond medical school.

To ask people who have incurred that kind of debt to then work for salaries that are one-half, one-third or one-quarter what they might work for in academic institutions certainly does place us under an added burden when it comes to attracting and retaining people.

Senator MIKULSKI. What do you think about that, Dr. Wyngaarden?

Dr. WYNGAARDEN. I think it is an important and serious problem. I would stress, however, that it is not limited to the NIH. We have been concerned for a number of years about the declining interest of physicians in academic medicine and research careers. There has been some improvement in the statistics on physicians entering research in the last few years, but one of the negative factors is the debt load. It is intensified if they come to the NIH over academic institutions at some stage, although our starting salaries at the NIH are reasonably competitive. It is as individuals move through the system that we can't increase their salaries to maintain a competitive position. Salaries in universities have continued to move upward at 6 or 8 percent per year; we have been frozen now for eight years or more.

We also have the biotech industry that has come into the picture.

Now, one of the functions of NIH has always been to train people who go into the universities and go into industry, but we are losing people faster than we can replace them now, and although it is not a melt-down situation at present, it is an important problem, and we have to give it attention if NIH is to maintain the superstars such as Steve Rosenberg without losing them over the next decade.

Senator MIKULSKI. Would you think debt reduction over a period of time—if those talented young men and women came to NIH, I am sure you would want them for a period of more than two years; you would want them, if not for a lifetime, at least for seven, eight years.

Dr. WYNGAARDEN. Yes, the successful ones, of course, we want to keep a long time.

Senator MIKULSKI. Well, let's talk about that, and let's talk about a continuum. For example, if Dr. Rosenberg were on the faculty of Johns Hopkins, where he received part of his education, he would have a faculty appointment. That means if one of those genius daughters wanted to go to Hopkins—and then they also have, I be-

lieve, reciprocity at other academic institutions—the Rosenberg whiz would have a scholarship; am I correct in that?

Dr. WYNGAARDEN. That certainly is the case for most academic institutions that would cover part of the cost of tuition.

Senator MIKULSKI. Well, what do you think of the idea, then—and I am really going to lay this out and I would really like, Dr. Wyngaarden, for you to explore this with the staff, and in fact I would be happy to in the future come out to a roundtable at NIH for further discussion, because I think this is really a critical national problem.

But let's just say, Dr. Hinshaw, Dr. Rosenberg, you're just out of school, and you come to work at NIH. You would be looking forward to some type of steady, methodical debt reduction over a five- or seven-year period.

Now, all of a sudden, here you are, 48 years old, and your children are ready for school. What about some type of reciprocity between NIH and its affiliated institutions having the same treatment of people as if you were on the faculty? Do you think that would help?

Dr. ROSENBERG. I think that would be a marvelous incentive.

Senator MIKULSKI. Participating institutions with NIH—and I can't wait for Steve Muller to call me up on this—but I'm groping for ideas, and I am just laying this out more as a brainstorm question.

But do you think that would then help, that if you, as a good father, and Dr. Hinshaw—I don't know if you are married—if you just thought that you were going to help your kids, and that you were not sacrificing your children's future while you were trying to make sacrifices for science—it is one thing for you to sacrifice yourself or your financial achievement, but I am sure as parents, you would not want to sacrifice the future of your children to have an education comparable to your own.

Is that one of the nubs here?

Dr. ROSENBERG. I think you have hit on an extremely important point. Certainly, when I look at many of the dedicated scientist colleagues at the NIH, they are willing to adapt lifestyles that are consistent with the many virtues of being at the NIH. But when it comes to the issue of educating their children, that tends to be the time when many of the very talented scientists leave the NIH. And I think a plan such as the one you have mentioned would be of great benefit, especially if you could institute it in the next 18 months. [Laughter.]

Senator MIKULSKI. I am good, Dr. Rosenberg, but I don't know if I'm that good.

Well, I would really welcome additional ideas and comments on this. I think it would be superb—if we could begin to crack this by putting our thinking caps on, I think the national contribution we could make could be as dazzling as some of the current research, because without the next generation, retention of the masters in the field in the next generation, we are going to be at risk.

Is that the same for our colleagues in nursing, Dr. Hinshaw?

Dr. HINSHAW. Yes, I would agree with that. There has been a task force in the NIH Office of the Director that has been looking

into different benefits and packages that could be used for professional practice and for professional rewards for nurses.

Senator MIKULSKI. Well, Doctor, I have been quizzing your people here, but we would really look forward to the report of that specific task force. This is one Senator who would really like to follow this right on through.

Also, as we know, the scholarship benefits that some students have gotten are now being taxed; am I right in that?

Dr. WYNGAARDEN. Yes, that's true.

Senator MIKULSKI. And we are trying to repeal that.

Dr. WYNGAARDEN. You are correct. That was lost in the last tax revision. The exemption from taxation of $3,600 per year for a maximum of three years was possible until two years ago.

Senator MIKULSKI. And that $3,600 is $3,600 to graduate students.

Dr. WYNGAARDEN. Yes.

Senator MIKULSKI. The Chair would like to welcome one of the most outspoken advocates for NIH, a good friend until Maryland could get its own Senator here to work a one, two, punch, Senator Weicker of Connecticut.

We have just been talking about NIH and its needs and some of the work force needs.

Senator Weicker, if you have any questions for this panel, we would be happy to have them, or we are getting ready to move on to the next panel—or, would you like to make an opening statement?

Senator WEICKER. Thank you very much.

I ask that my opening statement be placed in the record in its entirety.

Senator MIKULSKI. Without objection, so ordered.

Senator WEICKER. I thank the Chair for your kind remarks.

First of all, I want to compliment Dr. Wyngaarden on his extraordinary leadership of the National Institutes of Health. I think he has done so in a way that has not necessarily been easy over the years, trying to somehow balance out the differences between the Administration and the Congress and yet maintain the NIH in terms of integrity of thought and funding.

My problem, which I suppose we can discuss—and I don't want to get into it too deeply here, because I will have my opportunity to address all of you in the course of the appropriations hearings—my problem is that even though there seems to be a small increase requested by the Administration in the funding for the various institutes, still in terms of overall priority, it seems to me to leave the NIH somewhat short. And I get bothered by the fact that, whereas the funding has increased, the personnel have decreased, while it would seem to me need is on the increase. So I am trying to understand how that all works out.

It is also my understanding that in its request this year, the grants are again down from what was the case last year.

I just want to make certain that we have plenty of leeway in the authorization so that there can be adjustments in the appropriations process. I don't want to wed myself, in other words, to a figure here that in effect forecloses adequate action at the appropriations level.

Now, would you just comment as to whether you feel the authorization is adequate?

Dr. WYNGAARDEN. First of all, Senator Weicker, thank you for your generous remarks.

There are two areas of this reauthorization bill, or two areas of NIH authorization, that require specific reauthorization for us to continue—that is, the National Research Service Award Act, which supports training, and the Medical Library Assistance Act, and then certain specific authorities in the Heart Institute and the Cancer Institute.

With respect to training, we are at present bouncing right up against the authorization ceiling of dollar allowances. And I think in the reauthorization process one would need to look at the anticipated costs of training over the next three to five years, whatever the length of the bill.

The specific figures that we estimate for the costs of training in this next year, I believe, are about $340 or $345 million. The authorization limit suggested, I believe, is $350 million, which is getting very, very close in the first year. So that would be one specific area.

The others, I think, are the necessity for reauthorization in order to proceed. In times when authorization lapses, we fall back on the section 301 authority of the 1944 Public Health Service Act to continue all of the general research that we do. But training authority under that bill was cancelled in 1974 and must be specifically reauthorized, and the Medical Library Assistance Act was judged not to come under that. So those are two that specifically require attention.

Senator WEICKER. All right. Again, I know you have many panels before you, Madam Chairman, and I will have an opportunity to get into the financial details. Again, I want to thank all the members, and Dr. Hinshaw and Dr. Rosenberg, for all their efforts. It is not a lack of interest on my part, but I know you've got a lot of ground to cover, and I am going to have my swing at the pitch here shortly. So I have no further questions at this time.

Senator MIKULSKI. Thank you very much, Senator Weicker.

As we review the authorization, and knowing of your own thoughts as to where we are heading on appropriations, maybe we could dovetail them a lot more so there is not a gap between authorization and the type of appropriation we would seek.

Well, the Chair thanks this panel for a very informative briefing on NIH, where it is and on the work force shortages that we are facing nationwide in nursing, and particularly those in the clinical aspects of biomedical research.

We thank this panel, and we will now move on to the next.

Dr. WYNGAARDEN. Thank you.

Senator MIKULSKI. We will now move on to the facilities construction panel, and we would ask Dr. Chase Peterson and Dr. David Satcher to please come to the witness table.

We thank the panel, and Dr. Peterson, your Senator, Senator Hatch, is tied up in some other very crucial hearings, and he has a dazzling introduction for you that he wants me to read. So I am putting on my "Hatch hat"—not my "Hatch Act hat", but my "Hatch hat"—to say that Senator Hatch is "pleased to introduce to

the Committee today Dr. Chase N. Peterson, President of the University of Utah."

"The University of Utah is one of the Nation's leading biomedical research institutions and has been on the leading edge of biomedical technology. Dr. Peterson has played a major role in this effort, beginning with his involvement in artificial heart research that culminated in the development of the first implantable artificial heart."

Dr. Peterson, we look forward to hearing your views on the proposed reauthorization of the NIH and specifically the provision of the authorizing construction for research.

Dr. Satcher, we welcome you, as the President of Meharry Medical College, a distinguished institution and a member of a very unique set of institutions of historically black colleges, and we look forward to your unique perspective as well as your broad-based clinical and academic background.

Dr. Peterson.

**STATEMENTS OF DR. CHASE N. PETERSON, PRESIDENT, UNIVERSITY OF UTAH, SALT LAKE CITY, UT, ON BEHALF OF THE ASSOCIATION OF AMERICAN UNIVERSITIES AND THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND-GRANT COLLEGES; AND DR. DAVID SATCHER, PRESIDENT, MEHARRY MEDICAL COLLEGE, NASHVILLE, TN**

Dr. PETERSON. Madam Chairwoman and Senator Weicker, I appreciate that.

I am President of the University of Utah. I appreciate this is a heavy use of your time and, quite frankly, as a citizen, I appreciate your willingness to collect this expertise and to give voice in a democracy.

There are a lot of people whom I work with who feel they have no voice, and you are taking the time to give us voice and I hope, through us, them.

I am here to testify on behalf of my colleagues at the University of Utah on the Association of American Universities, the AAU, the National Association of State Universities and Land-Grant Colleges, the NASULGC, whose 176 members include most of the research universities we are talking about, and also the Association of American Medical Colleges, the AAMC. They also support the recommendation that we are advancing.

You and your staff have my written testimony. Let me provide a brief personal summary of these views.

We are grateful to this Committee in considering this critical subject and particularly applaud Title I of Senator Kennedy's reauthorization legislation. We thank those in this room who have served on staff for that purpose.

I want to simply address three points: the need, the value, and the means.

On the need, since World War II, we have had a flowering of biomedicine in this country and the world. We are the better for it individually and as a nation, biomedical science is a singular leader in national productivity. Stop and think about where we lead the world in productivity, and you can't use up too many fingers. You

can start with biomedicine, and I want to emphasize this a bit later.

The infrastructure, that is, the bricks and the mortar, were supported Federally back in the 1960s, but we have really had no support since then of a comprehensive nature. You simply cannot have a university without a library or classrooms; you can't have a symphony orchestra without a hall, and you can't have biomedical research without laboratories.

Our capacity is now wornout and insufficient. The University of Michigan sent around a memo the other day saying, "The inventory of space is completely depleted," and no one was allowed to submit any proposal for research unless they could come up with their own space.

The University of California, in their summary, has a $4 billion backlog of space needs.

At the University of Utah, it seems even larger, but the numbers are smaller. We have to spend $300,000 per year in rent, to buy space around town, essentially, off-campus. That is a very inefficient way to conduct research.

The AAMC has estimated we have about 18 million square feet of research space, and if you figure that 5 percent of that has to be renovated every year, that costs somewhere in the range of $250 to $300 million.

So that's the need, and it is very clear, the value.

America is indeed flagging in many areas of world competitiveness. In biomedicine, we have been the leader. And it strikes me as exceedingly foolish to allow that leadership position to wither.

Second, as respect to value, there is a continuing health care revolution, and it is even more important now, as the world and human health problems become more complex. There is no place to hide now in this world from health problems.

And finally, the means. Recently, NIH gathered a working group in response to Congress' request. We met three or four weeks ago; we don't have our final report, but the contents of our meetings have been communicated to many staffs.

Let me quote one paragraph from our preliminary report: "For almost 20 years, Federal support for the Nation's effort at maintaining the physical infrastructure for biomedical research has been negligible. There is a need for strong and well-defined Federal leadership and a dependable and long-term flow of funds for new construction, renovation and renewal and replacement of obsolescent equipment."

There has been great pressure to earmark. And if you would like to talk about that some more, I would be very pleased to do so, because I think it is an important issue that needs to be thought through very carefully. That is not the answer. And yet many of our best institutions and even more of our emerging institutions have sought earmarked funds in the absence of a legitimate program that they could appeal to.

We support a comprehensive program, and it has five points.

One, the NIH should be granted construction funding authority for biomedical research. NIH is a jewel in American history. It has done a good job; it has done it with high standards; it has done it with fairness. You will not find many knowledgeable critics of the

history of NIH, and we think they would be a good place for this to be placed.

Second, NIH authority should be centralized. We would encourage it to be with NIH generally, not necessarily widely distributed within the groups of NIH, the institutes.

Third, we think the award process should be governed by peer merit review with clear criteria. The criteria are not only the criteria of existing merit, but the capacity for excellence. We need to recognize institutions of emerging excellence. Let me try to amplify on that.

I think there is a great American tradition, and my father and I came up through that—namely, people who were on the outside who did not ask for admission to the inside by having the inside lower their standards, but rather, through preliminary efforts on our part, were able to prepare ourselves for preliminary entrance, if you will. I am talking about entrance to college, I am talking about my father leaving the lumber yards of Oregon in 1900 and going to Cornell.

What we are talking about in this country is intellectual mobility—high standards, but a capacity for everyone to enter. Now, if you are going to maintain both high standards and access, how do you do it?

It seems to me we do not need to have simply a nation of haves and have-nots. We can have a nation of haves, of, if you will, immediate have-nots, but also those people who are have-nots who have made the preliminary steps to prepare themselves to be haves.

I am talking about people who, brick by brick, have developed emerging excellence and are then prepared to use more resources. And I am comparing that to the naivete of thinking you can dump bricks on people and make them excellent. They have to show the initial effort themselves.

Fourth, institutions should be required to match any Federal grant. We think that a 50–50 grant generally would be an appropriate way to magnify the use of the money and to also put proof in the pudding of those institutions who are serious about doing the research.

We also think there should be some provision for flexibility in programs of high national interest, especially renovation of animal care facilities and safety, the emerging excellence I talked about, and maybe special facilities for emergencies, as in the AIDS problem now.

Fifth and finally, we think that indirect cost recovery should fund facility depreciation completely. If we can do that—and this is funding the non-Federal aspects of it, not the Federal, of course; that would be double-dipping, in a sense—if this can be done, we can avoid the problem 30 and 40 years from now that we are now facing.

That is the substance of my comments, Madam Chairperson. I would be pleased to take any questions.

[The prepared statement of Dr. Peterson, with an attachment and responses to questions submitted to him, follow:]

AAU
NASULGC

Testimony
Of
President Chase N. Peterson
University of Utah

on behalf of
The Association of American Universities
and The National Association of State Universities and
Land-Grant Colleges

Before the Senate Labor and Human
Resources Committee

March 29, 1988

Association of American Universities, One Dupont Circle, Washington, D.C. 20036 (202) 466-5030
National Association of State Universities & Land-Grant Colleges, One Dupont Circle, Washington, D.C. 20036 (202) 293-7120

Mr. Chairman, I am Chase N. Peterson and I am President of the University of Utah. I appreciate this opportunity to testify on the subject of biomedical research facilities. My statement today is presented on behalf of my colleagues at the University of Utah, the Association of American Universities, and the National Association of State Universities and Land-Grant Colleges whose members include 176 universities, representing most of the nation's research universities. The Association of American Medical Colleges (AAMC) also supports the recommendations embodied in this statement.

In my testimony today I will discuss the need for a research facility construction program and the implications for the continued quality of biomedical research without such a program. I want to emphasize from the outset that we advocate a program in which the colleges and universities of this country can participate in partnership with the federal government in revitalizing research facilities. I firmly believe that without such a program we cannot keep this Nation's biomedical science at the cutting edge. Investment in improved facilities is essential to maintain our preeminence in biomedical research, one of only a few areas where this Nation still holds a position of international superiority.

We are grateful that the Subcommittee is considering this critical subject. In particular, we applaud Title I of Senator Kennedy's NIH reauthorization legislation: "Biomedical and Behavioral Research Facilities." This legislation recognizes the necessity to begin to address the nation's biomedical research facilities deficit. While support for biomedical research grants has continued to grow, support for the essential infrastructure for this research has virtually disappeared. The result has been a seriously deteriorating research environment and an erosion of the capacity of universities to host federally sponsored research.

A federal role in support of research facilities is not a new concept. As recently as the early 1960's, the United States had a strong commitment to the expansion of the Nation's academic research facilities, which resulted in the passage of several acts of enabling legislation. These initiatives have since expired, and today we are faced with the critical need to renovate and reconstruct our Nation's academic research infrastructure. If our nation is to continue to be at the forefront of biomedical research, we must redefine research support to include the maintenance of the research infrastructure.

Recently the NIH, in response to a Congressional request, convened a working group of outside experts to advise the Director on how to address the research facilities deficit. I am a member of that working group. Public testimony from the meeting reinforced several points. A variety of agencies, groups and committees, both public and private, have expressed their

concerns regarding the state of the research infrastructure. Not surprisingly, because of differing priorities among groups, there is some lack of consensus on issues related to infrastructure, such as the need for expanded versus renovated facilities, or the best mechanism for support. One issue on which all parties do agree involves the need for the development of a well-coordinated, long-range strategy for support at the Federal level. All parties agree that research is hampered by aging and obsolete research facilities and instrumentation, and assert that the need to reduce the backlog of maintenance, renovation, and expansion of these facilities is crucial.

While the Working Group's report is not yet final, let me quote two of the recommendations I find most pertinent here:

> "For almost 20 years, Federal support for the Nation's effort in maintaining the physical infrastructure for biomedical research has been negligible. There is a need for strong and well-defined Federal leadership and a dependable and long-term flow of funds for new construction, renovation, and renewal and replacement of obsolescent equipment."

And, further,

> "NIH should be given an overall construction authority to address research facility construction needs. This authority should not supersede existing institute authorities, nor should it preclude the establishment of new authorities for other institutes."

While there is universal agreement that we suffer from a facilities deficit, it is useful to understand better how these problems affect the conduct of research. I have appended to my testimony a copy of a University of Michigan Dean's memorandum (ATTACHMENT I) advising all researchers that the "inventory of research space is completely depleted" and that no grant applications may go forward absent a plan for space. I also understand that the University of California alone has a backlog of $4 billion in all facilities.

At the University of Utah, for example, we are forced to spend nearly $300,000 annually to rent research space off campus for the School of Medicine, the College of Pharmacy, the College of Nursing and the Artificial Heart Research Laboratory. We rent this space because we have been unable to attract capital funds to construct appropriate facilities on campus. To do otherwise means that important research efforts in medicinal drugs and drug delivery, cancer research, and continued development of the totally implantable artificial heart, etc., would go undone.

We are aware that the assessments of the very large research facilities deficit frequently serve to discourage attempts to address this shortfall. The

problem, however, will not disappear on its own. Further, we believe a renewal of federal commitment is an essential factor in coordinating and motivating private sector commitment to refurbishing the research infrastructure.

At least 60%, or approximately $9 to $10 billion, of the Nation's basic research of all types is conducted at approximately 100 research universities. The total scientific research effort in the U.S. in 1987 was about $15 billion. Ten billion of that total came from the federal government, $3 billion from corporations and the remainder from state government and various non-profit organizations. The percentage of our total expenditure on biomedical research that is supported by government parallels that of government-supported research in general. The National Institutes of Health fund approximately 75% of the biomedical research conducted in universities, making the NIH an especially appropriate and knowledgeable source of funding for facility renovation and new construction.

The AAMC has developed a model to estimate the cost of maintaining the current academic research facilities inventory within the Nation's medical schools. The details of this analysis (AAMC testimony before the NIH Working Group, ATTACHMENT II) is appended to my testimony. The AAMC concludes that an annual investment of $301M is needed to prevent deterioration of the current medical school research space devoted to NIH sponsored medical research.

Many universities use a patchwork of funding mechanisms to finance their biomedical research facilities, including tax-exempt borrowing, charitable giving, corporate support, return on operations, and private foundation monies. Two of these funding mechanisms, tax-exempt borrowing and charitable giving, were severely compromised by the 1986 changes in the tax code. The tax-exempt bond market is now closed to numerous research universities because of the $150 million cap on private university borrowing. I should add at this point that the borrowing cap on private universities imposed by the "tax reform" legislation is also troublesome to public universities. That measure disturbed a long-standing American tradition of equity in our higher education system between public and private universities, and should be removed from the tax code. Although recent changes in the economy are also a factor in a decline in charitable giving, such monies have been extremely difficult to raise for capital projects. To the extent these institutional funds are used to maintain and/or expand facilities, they are not available for other major university responsibilities. Assuming indirect costs are fully reimbursed, in conformance with federal policy, it should be understood that the government will pay for some of these facilities costs. However, it is important to note that because of interest costs, borrowing to fund new research facilities is a much more expensive

mechanism than a program of direct grant support.

With regard to full reimbursement of indirect costs, there are some serious points to be made. If institutions must borrow, especially outside the tax-exempt bond market, in support of the national mission and federally funded research, indirect cost recovery rules must recognize that fact and fully fund depreciation. It is also well known that the present policy of direct and indirect cost reimbursement does not fund the full cost of research experienced by a university.

The rules for indirect cost recovery are complex, and as difficult for federal agencies to administer uniformly as they are for us to understand. If indirect cost recovery is to be used to reimburse universities for the capital cost of research facilities, and for equipment actively used for federal sponsored research, then the rules for reimbursement must be clarified and applied equitably throughout the country. Full funding of generally accepted depreciation schedules for research space and facilities through indirect cost recovery is a way of financing such needs. (However, using this mechanism requires that universities go into the financial marketplace for the money.) For private universities who are constrained by the $150 million limit in tax-exempt borrowing, such money is particularly costly.

As you may know, Mr. Chairman, the Association of American Universities (AAU) and the National Association of State Universities and Land-Grant Colleges (NASULGC) have been concerned with the increasing number of earmarked appropriations of federal science budgets for specific university projects. Although our associations have expressed concern about the process of earmarking, many of our members have pursued such funds. These institutions have pointed to the hard reality that there have been no opportunities to compete for funds at the federal level in support of research facilities. Formal legislation which would remedy this problem and provide the necessary funds is certainly a better approach.

It is important to note that the AAU and NASULGC are not alone in this concern. Frank Press, President of the National Academy of Sciences, recently pointed out that the scientific community views the increase in earmarking "with dismay and alarm," warning that when Congress mandates money for a specific university project, it "creates new incentives and pressure for other institutions to seek similar treatment from the Congress." In short, we believe the practice of earmarking funds to be an inefficient and less effective method of distributing federal research dollars.

The current inventory of research space in which NIH extramural research is conducted has deteriorated and must be upgraded as soon as possible. Last year and again this year, the Ad Hoc Group for Medical Research Funding, a

coalition of approximately 170 academic associations, scientific societies, and voluntary health organizations, is requesting funds for repair, renovation and replacement, not new facilities. The Ad Hoc Group requested that a "down payment " of $200 million be provided for facilities in FY 1988 and $250M in FY 1989.

During the recent NIH meeting on the state of academic research facilities, the AAMC pointed out, "Simply maintaining the current inventory is very costly. But maintaining the inventory is just the beginning. The survey of animal facility needs, conducted by the National Academy of Sciences Institute of Laboratory Animal Resources (ILAR) now almost a decade old, indicated the need for $500 million to bring animal facilities up to standard. Despite interim assistance from the NIH for animal facilities, the revision of this estimate, now in progress, will not likely be smaller. In most of our institutions, research space is intensively used and the current inventory is not really even adequate for the programs currently housed in them. Expanded research activities cannot be mounted without new facilities."

The time for change is upon us. What is urgently needed is federal support for the infrastructure of the biomedical research enterprise--support for remodeling, renovating, modernizing, and when necessary, replacing what exists, and for building additional space when federal research investments increase.

For these reasons, we applaud Senator Kennedy's proposal for a new facilities initiative and urge the Committee to enact legislation to meet the following goals:

1. NIH should be granted construction funding authority for biomedical research.

2. NIH funding authority should be centralized.

3. The award process should be governed by merit review with clear criteria for awards. The criteria should take into account the need to broaden the base of biomedical research and thereby acknowledge the responsibility to institutions with emerging excellence in research. New construction authority could include provisions for "emerging" institutions, taking into account such factors as:

   (I) the underrepresentation of minorities in health sciences careers;
   (II) the health status deficit of a large segment of the population; or
   (III) a regional deficit in health care technology or services that can adversely affect health status in the future.

It is essential, however, that none of these provisions override merit review. Rather, these factors should be considered in the process of establishing funding priorities.

4. Institutions should be required to match federal funding in some systematic way. In addition, consideration should be given to a flexible match with a greater federal portion allowable for projects in categories of national interest. These categories could include: facility renovation to meet federally mandated requirements for animal care or health and safety; facilities at "institutions of emerging excellence"; or specialized research facilities for research on public health emergencies, such as AIDS. It should be recognized that previously available options for the generation of matching funds have been curtailed; it is critically important that the Congress remove the $150 million cap on tax-exempt financing for private universities. At a minimum, borrowing for research facilities should be permitted to exceed the cap.

5. Indirect cost recovery should fund facility depreciation fully. Of course, indirect cost recovery would continue to be disallowed for any portion of the cost of a facility directly funded by the government.

Mr. Chairman, thank you for this opportunity; I will be pleased to respond to your questions and comments.

ATTACHMENT I

The University of Michigan
Medical School

Office of the Dean

October 12, 1987

MEMORANDUM

TO: Department Chairmen
Center and Unit Directors

FROM: Joseph E. Johnson, M.D.
Dean, Medical School

Irwin J. Goldstein, Ph.D.
Associate Dean for Research and Graduate Studies

SUBJECT: Research Space

I write to inform you that the Medical School has completely depleted its inventory of research space. There is no longer any uncommitted space available either in existent structures or in any buildings under construction at this time. All research programs developed by a Medical School unit must include a plan for the utilization of space presently in that respective unit's inventory. Therefore, all grants or contracts forwarded to Medical Administration for processing must be accompanied by a plan for assignment of appropriate space within that unit. At this time we envision no exceptions to this policy.

The implications of such a situation are significant for our dynamic and growing research enterprise. It should be noted that a Task Force assigned by the Dean to address issues of space allocation and reallocation is in the process of producing a final report outlining guidelines for research space utilization. In the meantime, we seek your support and advice in resolving this dilemma, while at the same time we must insist on your compliance with this policy.

IJG:slb
0197/13
xc: George D. Zuidema
Linda S. Wilson
Dean's Staff
Department Administrators
Martin Tobin
Kathy Hilden
Research Space Task Force

ATTACHMENT II

# STATEMENT

OF THE

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

On

A Pilot NIH Health Research Facilities Program

Presented
February 9, 1988
National Library of Medicine, NIH Bethesda, Maryland

By

Richard Janeway, M.D.
Vice President for Health Affairs and Executive Dean
Bowman Gray School of Medicine of Wake Forest University

Good morning!

I'm Dick Janeway, Vice President for Health Affairs and Executive Dean at Bowman Gray. The AAMC has not yet had an opportunity to develop an official position on the charge to the Director, NIH, included in the recent report from the Senate Appropriations Committee. My representation of AAMC views, that is, the views of 127 medical schools, over 435 teaching hospitals and 85 academic societies, is thus unofficial but based on knowledge and experience accrued during my service to the Association on the Administrative Board of the Council of Deans from 1977 to 1984, the Executive Council from 1977 to 1986, and as Chairman-elect, Chairman and past Chairman of the AAMC Assembly from 1983 to 1986.

I hardly need tell this distinguished group that American universities have been linked in a partnership with the Federal Government for almost half a century to carry out a national agenda in basic and applied research. Perhaps the most successful element of that partnership has been the one between biomedical scientists in medical schools and teaching hospitals on the one hand, and the institutes and divisions of the National Institutes of Health on the other. The academic community looks forward to a continuation of this history of accomplishment of our partnership, and anticipates ever more dramatic advances toward the solution of heretofore intractable problems of disease, disability and premature death. Today's focus is on one of the resource requirements essential for progress,---research facilities.

The clear objectives of AAMC institutions in terms of the issues before the consultants are shown on the next few slides:

- Our first challenge (Slide 1) is to have a physical plant in adequate condition to conduct the research that the NIH is mandated to support,

a plant whose functionality must be maintained in the face of rapidly changing requirements imposed by scientific progress.

- Then (Slide 2) the facilities must also be in compliance with a large number of externally established standards, regulations and guidelines related to the welfare of experimental animals, the health and safety of laboratory workers, and the protection of the environment.

- Finally, (Slide 3) our institutions must be prepared to respond to new challenges as the NIH is given the resources to expand its scope and intensify its efforts. Research on AIDS is an urgent contemporary example.

What is the magnitude of the problem? How can it be costed? The AAMC staff has led me through an exercise that helped me get a better grasp on these questions and may interest you. Most of the calculations are based on data, but a couple of assumptions have been necessary. The latter will be explicitly noted; they are, in my opinion, reasonable.

- According to its 1986 "Data Book", the NIH, in FY 1985, awarded $3.211 billion to institutions of higher education for biomedical research, development, training and construction. Of this, $2.223 billion was awarded to schools of medicine. In addition, $0.259 billion was awarded to non-profit hospitals. (Slide 4) For illustrative purposes, the subsequent analysis will be limited to the medical school component.

- How much space have medical schools dedicated to NIH-funded research? The NIH designed pilot survey of research facility needs, conducted in 1985 by Abt Associates in 9 universities and 9 independent research

institutes and nonprofit hospitals, yielded one statistic that helps get a handle on this question. The response to the questionnaire showed that in the medical sciences, academic institutions expended $121 per net square foot (NSF) of space (Slide 5). Thus, $2.223 billion of expenditures correspond to an NIH-dedicated space inventory of 18.373 million NSF (Slide 6) in the nation's medical schools, a not inconsiderable amount.

- Empirical studies about the condition of this space are underway under the aegis of the National Science Foundation. The questionnaire is in the field and many of you are probably reviewing your institution's response. But even without this data, it seems reasonable to assume that if these facilities are to be kept functional, they should be renovated and modernized on a scheduled cycle. The first judgment call in this presentation (Slide 7) is that major renovations are required about every 20 years to maintain functionality; if your judgment or experience differs, the calculations that follow would have to be changed appropriately. A 20 year cycle assumes that 5% of the medical school space inventory, or 919 thousand NSF should be remodeled/renovated/modernized every year, if AAMC institutions are to be fit places to conduct NIH-supported research.

- What's the annual dollar investment required to "stay in shape?" Cost data are scarce. The AAMC was provided some relevant information about the experience of NCI's construction program. Renovation costs depend on the type of laboratory (Slide 8) and vary considerably. For this exercise, the assumption used was that, in medical schools, the average space mix included 40% standards labs, 40% multidisciplinary labs and 20% clinical research facilities, with a weighted average

cost of $328/NSF (Slide 9). Again, if your judgment or experience differ, you can easily recalculate.

- o Multiplying 919 thousand NSF of space by an average renovation cost of $328/NSF reveals that an annual investment of about $301 million is needed to stay in shape. ( Slide 10) That is a very large investment and will likely remain large, even if these calculations need revision. If that investment either was and is being made by someone, our institutions are thus in good shape; if it was not and is not being made, the infrastructure is deteriorating.

The point of this exercise is to emphasize that simply maintaining the current inventory is very costly. But maintaining the inventory is just the beginning. The survey of animal facility needs, conducted by the National Academy of Sciences Institute of Laboratory Animal Resources (ILAR) now almost a decade old, indicated the need for $500 million to bring animal facilities up to standard. Despite interim assistance from the NIH for animal facilities, the revision of this estimate, now in progress, will not likely be smaller. In most of our institutions, research space is intensively used and the current inventory is not really even adequate for the programs currently housed in them. Expanded research activities cannot be mounted without new facilities.

Who is responsible for the infrastructure? Obviously, facilities are an indispensable requirement for research and thus, in the AAMC's view, a legitimate research cost. The facilities for biomedical research that presently are in operation in our institutions are there, mostly, to accommodate NIH research investments. Without NIH support, a vast amount of space would lie fallow. The Association's argument is that the NIH should pay

for the infrastructure costs of its programs in our institutions. It should have been paying to keep the plant in shape lo these many years, and it should also have paid for the cost of the space constructed to house the 80% expansion of programs, i.e., the constant dollar increase in annual expenditures, that has occurred since the last research facility construction grants were made in the early 1970's. This argument is only a specification of the Association's general policy that in this day and age, the federal government should pay the full reasonable costs of the research it sponsors in universities.

To the extent that the plant has been maintained and expanded, it has been done almost entirely by the grantee institutions, at very substantial cost to, and sacrifice of, their responsibilities: to other medical school and teaching hospital claims on resources; to their non-medical faculties; their non-biomedical science and non-health professions students; and to the society that has authorized and chartered them for a broad range of other objectives.

The time for change is upon us. What is urgently needed is federal support for the infrastructure of the biomedical research enterprise---support for remodeling, renovating, modernizing, and when necessary, replacing what exists; and for building additional space when federal research investments increase.

Let me now yield to Dr. Louis J. Kettel, Dean of the Medical School at the University of Arizona for the last 10 years and just beginning his second month on the AAMC staff, to discuss the nature of the programs the AAMC thinks appropriate.

## FACILITY GOALS OF AAMC INSTITUTIONS

MAINTAIN CURRENT PHYSICAL PLANT FOR FEDERAL RESEARCH AT OR NEAR "STATE OF THE ART"

COMPLY WITH STANDARDS, REGULATIONS, GUIDELINES ON
- GOOD LABORATORY PRACTICE (FDA)
- ANIMAL CARE (NIH/PHS)
- PERSONNEL HEALTH AND SAFETY (OSHA)
- ENVIRONMENTAL PROTECTION (EPA)

RESPOND TO EXPANSION IN SCOPE AND/OR INTENSITY OF FEDERAL EFFORT

## MAGNITUDE OF THE FACILITIES PROBLEM

NIH (FY 1985) EXPENDITURES (FROM NIH "DATA BOOK") TO

| | |
|---|---|
| HIGHER EDUCATION (TOTAL) | $3.211 BILLION |
| MEDICAL SCHOOLS | 2.223 BILLION |
| NON-PROFIT HOSPITALS | 0.259 BILLION |

RELATIONSHIP OF EXPENDITURES TO SPACE (FROM JULY 1985 NIH/ABT ASSOC. SURVEY)

MEDICAL SCIENCES: $121.25 PER NET SQUARE FOOT (NSF)

MEDICAL SCHOOL SPACE INVENTORY DEDICATED TO NIH RESEARCH:

$2.223 Billion ≑ $121.21 PER NSF = 18.373 MILLION NSF

ANNUAL AMOUNT OF SPACE SCHEDULED FOR RENOVATION

| CYCLICITY | TO BE RENOVATED | |
|---|---|---|
| | %OF INVENTORY | NSF |
| 16 YEARS | 6.6 | 1.213 MILLION |
| 20 YEARS | 5.0 | 0.919 MILLION |
| 25 YEARS | 4.0 | 0.734 MILLION |

ANNUAL COST OF RENOVATION ON A 20 YEAR CYCLE

0.919 MILLION NSF X $328/NSF = $301 MILLION

## COST OF RENOVATIONS (FROM NCI DATA)

| TYPE | COST/NSF |
|---|---|
| STANDARD LABORATORY | $220 |
| BIOHAZARD CONTAINMENT LABORATORY | $240 |
| CLINICAL RESEARCH FACILITY | $200 |
| MULTIDISCIPLINARY FACILITIES | $500 |
| STANDARD ANIMAL FACILITIES | $600 |

## ESTIMATED WEIGHTED COST OF RENOVATING NIH-DEDICATED SPACE IN SCHOOLS OF MEDICINE

| TYPE | COST/NSF | %IN MIX | FRACTIONAL COST |
|---|---|---|---|
| STANDARD | $220 | 40% | $ 88 |
| MULTIDISCIPLINARY | $500 | 40% | $200 |
| CLINICAL RESEARCH | $200 | 20% | $ 40 |
| AVERAGE FOR MIX | | | $328 |

Responses of Dr. Peterson

1. NIH Senior Science Service

A Senior Scientist's Service would be successful in retaining scientists at NIH if it addressed the issues that lead to their leaving: substantially better salaries, at least competitive with those in the university community. Shortcomings in the scientific working conditions of NIH such as adequate numbers of lab technicians, the quality of instrumentation and laboratories themselves need responses. It is true that making employment at NIH more desirable for leading scientists would make it more difficult for universities to lure them away. This is not necessarily a bad thing. NIH should not be held as a research farm team for the university community. Having the top scientists in various disciplines working in the NIH intramural research program benefits the entire research community, not only in the United States but worldwide. Any shortages of first-rate scientists should be addressed by increasing training and scientist development programs.

2. AAMC Estimates

If I understand the AAMC statement, it is that more than $300M are required just to maintain facilities currently used in medical research sponsored by NIH. Because this level of funding will sustain and maintain only existing facilities, it would not be adequate to building more space or replacing old facilities that are no longer viable. It, therefore, would not resolve any backlog of need.

3. Matching Funds

Institutions should be required to match federal funds; history dictates that a 50% match has worked well. It is important to note, however, that for NIH facilities, many institutions matched federal dollars with well over 50%. A match is a useful device to insure institutional commitment, to ration funds only to those universities significantly engaged in research, and to motivate private sector and state resources. It must be recognized that the purposes of an NIH facilities program is not to enhance university's campus but rather to insure that universities engaged in the conduct of NIH supported research have the capacity in their research infrastructure to host this research adequately.

4. Instrumentation

Let me respond first on a positive note. For the past several years a number of federal agencies including the Department of Defense and the National Science Foundation have embarked on programs that enhance the quality of instrumentation on the nation's campuses either through direct grants to obtain instrumentation or through increases in the size of grants to permit instrumentation to be obtained that is needed to conduct the research in the projects funded. In absolute terms there is no question but that things have improved and continue to improve. In comparative terms -- compared to what is needed to conduct state-of-the-art research, we have a considerable way to go.

There are numbers of officials who have noted perhaps because of the dismay at

how costly facilities can be that a lot of good science can be done in a building with leaky roof. To some degree there is truth to this. But all of them will insist that you have got to have first-rate trained scientists using the most modern instrumentation if you are going to do research that is competitive with nation's around the world. Studies done during the past decade and the study being brought to completion at the National Science Foundation at the moment all focus on this significant shortfall. Yankee ingenuity has gone a long way in our laboratories as scientists make do with outmoded equipment and instrumentation, but there is much concern over the long-term implications of trying to compete with foreign scientists using instrumentation much superior to what is generally available in our own research laboratories.

5. Hard Data

We all prefer numbers and other data that can list at the bottom of the page precisely the nature of the problem or solution. I think, however, that when officials responsible for research at one of the nation's leading medical research universities notify the faculty that they have run out of space for more research and that, in effect, no more will be accepted unless something else is removed, that a truly serious problem exists. This is particularly true if comparable circumstances are being replicated across the nation. In my own institution difficult decisions have been made that clearly restricted the progress of worthy research activity solely because there was no adequate square footage available in which to conduct the research. The costs of research have been increased by the need to lease external space. It is also

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true that a formulistic approach would not answer the question. Given the amount of square footage devoted to university medical research, for example, how does the dollar per square foot invested in maintenance compare with comparable investments in industry and business. Or, how old does a laboratory have to be before it is entirely revamped so that it can do modern research? How would university laboratories fare in this area compared to those in business? What is the average age of a piece of equipment in the university laboratory compared to industry laboratories? And what is the average age of the laboratory as a whole? How many square feet per senior scientist, junior scientist, technician in universities and industry? I respectfully submit that this is fairly hard data on the nature of the problem and has been developed in several previous studies.

6. University Responsibility

Universities have worked to maintain existing facilities and to build new research facilities. Unfortunately, one of the major vehicles for financing such facilities: issuance of tax exempt bonds, was curtailed in the Tax Reform Act of 1986. While it is true that universities have a responsibility to provide facilities for research, there are several key points: the federal government has a long standing scientific policy agreement with universities to host federally sponsored research; one of the basic principles of this agreement is that the universities should neither gain nor lose because of this arrangement. Facilities costs are a real and growing part of this cost. Both the universities and the federal government bear the responsibility of choosing immediate expenditure in support of research and research personnel

while forgoing capital expenditures. We are at a crisis point when both partners must cooperate: hence a matching program.

The interrelationships between the federal government, state governments, private sources of support, the universities themselves is unique to the United States. It is complex, sometimes unwieldy, but it has worked with remarkable efficiency and productivity in areas of research during the past several decades.

The federal government is the instrument of the nation's citizenry. It makes decisions and judgments in behalf of the welfare of the citizens. This includes supporting the conduct of medical research with a goal of preventing and curing serious illness and disease. We have chosen in this country not to have all of this research conducted solely in federal laboratories. Other countries would have gone that way. We have chosen to use the wealth represented by the scientists in our universities to carry out this research across the entire country in the cumulative form of competitiveness to produce our usable knowledge. When the people of this country for their government decide that they must have the most modern war planes for the nation's security, they do not build these planes in federally owned factories. They enter into contracts with the private sector and these contracts are built with all attendant costs paid for by the people of the United States -- including profits. When the people who wish to buy knowledge may also wish to have the centers of knowledge creation reimbursed for their costs whether they be salaries or the equipment or physical environment.

The universities themselves, like the private corporations that build war

planes, benefit greatly from the research done on their campuses. A healthful environment for learning is created and maintained. Young students become apprenticed to senior scholars and then themselves become scientists. And for that reason the universities feel it is entirely proper that they participate in the overall costs of the conduct of research for the federal government. But it follows that it should never be the responsibility of a private university or a public university to undertake construction of a facility in which the main purpose would be carrying out an assignment requested by the federal government. In fact, the federal government only participated in supporting facilities construction for about a decade in the 1960's. It has been two decades since any new funds were appropriated for this purpose so that the universities would be able to fulfill their responsibilities to the federal government in conducting federally sponsored research. In short, assisting institutions in a matching cost facility program ought not be thought of as a federal problem, but it certainly is a federal responsibility.

7. Less prestigious institutions

This is an excellent question in all of its parts because it summarizes some of the uncertainties legislators have regarding the proper manner for distributing federal funds for research and related activities. The question cannot be responded to without first asking what is it that we are trying to accomplish? The Federal Government funds biomedical research to reduce morbidity and mortality, not to build universities. Therefore, a facilities program should provide facilities funds for those institutions hosting NIH research. We first must determine what the national objective is with regard

to any federally funded program. It is reasonable for some forms of federal programs to distribute funds on the basis of population. Others might distribute it on the basis of the number of fire departments in the state or fishing boats or lobster beds or anything else depending on the purpose of the program.

If you have a program designed to enhance quality medical research, then you want to first make certain that the funds go to institutions that would produce quality medical research -- the highest quality. Second, you might just as wisely want to have funds going to institutions that prospectively will produce quality research, schools that have shown by their own commitment and dedication the intention to become great medical research institutions. You could have other equally justifiable standards if you wanted to nurture minority scholars in the field of biomedical research you could quite properly have a highly disproportionate amount of funds flowing to a few institutions that have shown their capacity for carrying out that task. If you wanted to train people who are going to have careers doing research on the medical ailments of most Americans you might want to concentrate funds differently. The idea of "fair" may not fully apply anymore than "unfair" would apply. Utah, my home state, has no entitlement or any other kind of right to a submarine base just because there is a large body of water in the state. Arizona should not be thinking of a pine forest research facility in their borders. Contrary to what some Members of Congress have said over the years, medical research is not a melon to be cut up equally among states. It can be done that way, of course, with extraordinary amounts of waste and no real benefit to many beneficiaries of the dollars beyond the first impact of the funds. Fairness in distributing biomedical research dollars lies in the

obligations of the federal government to honor the citizens. Will they be better off in the long-term if the funds are placed in institution X or institution Y. The answer to this is not always obvious, but it can be studied, evaluated, and a genuine effort made to be "fair." Geographical distribution has a positive political ring to it and a justifiable ring in other ways. It is important for the federal government to look to the distribution of funds and to see what can be done, what ought to be done to make certain that unreasonable concentrations of dollars will not take place. The AIDS disease virus is not geographically distributed in the United States. AIDS research needs to be often close to where the disease's victims are located. Geographical distribution by itself simply has no place.

In short, which schools, East or West, should be considered irrelevant to the original purpose of getting the best biomedical research done for the country. If there is a second purpose, then geography could then be considered. Finally, peer review is clearly understood. It is intended to mean merit review. Members of Congress and not scientists are equipped to make political decisions. Scientists are usually the best equipped to make scientific decisions. A political decision made with consideration of the best scientific advice seems like the most wise approach to these programs.

8. Adequacy of the bill

The amount authorized in the bill is not adequate to solve the facilities problem nor do we think it was so intended. It is intended to help the facilities problem that has to be dealt with by states, private sources, and

universities along with the federal government.

9. Too restrictive

It is often argued that restrictiveness is like beauty, something in the eyes of the beholder. Facilities support programs need to be administered so that they achieve their aims as efficiently as possible and not make people jump through unnecessary, time-consuming and expensive hoops.

10. Congress and the scientific community

In essence the question is answered above. Scientists are best for giving scientific judgments. Congress is best for giving political judgments. And ultimately Congress has to make the final decision.

Senator MIKULSKI. Thank you very much, Dr. Peterson, for that excellent testimony.

The Chair would like to welcome to the hearing Senator Tom Harkin of Iowa and our own Senator Hatch—I read your introduction of Dr. Peterson.

Senator HATCH. Thank you. I appreciate that. I want to thank the distinguished Chairman for recognizing me at this time, and I want to thank Dr. Peterson, as well as Dr. Satcher and the others who are testifying here today. I am sorry I arrived here right as you finished, Chase. I really feel badly about that, but I am aware of your views, and what you said in your testimony.

Senator MIKULSKI. Senator Hatch, as the Ranking Minority, do you have an opening statement you wish to make, or——

Senator HATCH. I do thank you, Madam Chairman. I——

Senator MIKULSKI. We were about to hear testimony from Dr. Satcher.

Senator HATCH. Well, let me put my opening statement into the record at the appropriate place.

Senator MIKULSKI. Without objection.

Thank you, Senator Hatch.

Senator Harkin, we wish to welcome you as well. We know you will be chairing the panel right after Dr. Satcher completes his testimony. Do you have an opening statement you would like to enter into the record?

Senator HARKIN. Not right now, Madam Chairman. I'll just insert it in the record. Thank you.

Senator MIKULSKI. Thank you.

Dr. Satcher.

Dr. PETERSON. Madam Chairperson, if it is all right, I'll leave, then, and catch an airplane.

Senator MIKULSKI. Well, wait a minute.

Dr. PETERSON. Did you wish to ask questions maybe after both of us?

Senator MIKULSKI. Yes.

Dr. PETERSON. Oh, then, fine; I'll hold the airplane.

Senator MIKULSKI. Have you got your own? Let me take a look at that authorization again. [Laughter.]

Senator HATCH. What time is your plane?

Dr. PETERSON. I'll be okay; it's at 5:40 at Dulles.

Senator HATCH. Oh, you had better go.

Let's submit questions in writing, Madam Chairman.

Senator MIKULSKI. Yes, and we are running late. We do have a few questions for you. We'll submit them to your organization.

Dr. PETERSON. Fine.

Senator MIKULSKI. If you are trying to get to Dulles in this traffic, you have not met infrastructure needs yet. [Laughter.]

Thank you for your testimony.

Dr. PETERSON. It is an honor to be with you. Thank you.

Senator MIKULSKI. Dr. Satcher.

Dr. SATCHER. Thank you, Madam Chairperson and members of the Committee on Labor and Human Resources.

I am delighted to have this opportunity to testify in support of the reauthorization of the National Institutes of Health, with a spe-

cial focus on supporting the authority for extramural biomedical research facilities construction.

I am going to be very brief, and I am going to summarize my testimony, which you have, which will be for the record.

I participated with the NIH Study Group on February 9th and 10th which identified the need for extramural biomedical research facilities construction, and I strongly support that reauthorization.

I am representing not only Meharry Medical College, but the Association of Minority Health Professional Schools, which includes all of the predominantly black health professional schools except Howard University.

That group of institutions, I think as you know, has educated approximately 40 percent of all the black physicians and dentists in this country, approximately 50 percent of all the black pharmacists, and 75 percent of all the black veterinarians, and this Committee has been very supportive of concerns of the Association.

AMHPS has two special concerns relative to facilities reauthorization. The first one relates to the health status issue, and in 1985, then Secretary Heckler reported on the health status of blacks and other minorities in this country. Among other things, that report pointed out that infant mortality was twice as great, and that diseases like cardiovascular diseases, cancer and diabetes were significantly greater in blacks and other minorities. But the bottom line of that report was that every year in this country, there are 60,000 more deaths among blacks than would occur if blacks had the same age- and sex-adjusted death rates as whites—60,000 excess deaths per year!

But that report also pointed out that there was a specific need to accelerate the development of research infrastructures at institutions that were especially relevant to the training of minority health science researchers and relevant to dealing with health status problems in blacks and other minorities.

So our first concern is that in the authorization for research facilities construction that we remember this particular concern.

The second concern which the Association has is with the underrepresentation of blacks and other minorities in health sciences research. Despite the fact that blacks constitute 12 percent of the population, less than 2 percent of the health science researchers in the country today are black.

A good example of this is the fact that Meharry Medical College, which has a school of medicine and a school of dentistry, in 1972 started a school, of graduate studies and research. Since 1975, Meharry has graduated approximately 10 percent of all of the black biomedical scientists who have received Ph.D.s during that period of time.

That serves to point out not only the role of Meharry Medical College, but the serious problem which we have in this country in terms of blacks and other minorities in health science research.

With that background, then, the Association supports the authorization for facilities construction. We support peer review, and we support the use of scientific merit. But we also feel that it is very important that institutions of emerging excellence who have a special relevance to these problems of the health status of blacks and other minorities and also who have demonstrated an ability to

impact upon the under-representation of blacks and other minorities in the health sciences be given special consideration as having a special kind of excellence, which is very important in this country today as we look to the future in terms of health status, but also as we look at the issue of health science manpower for the future, and where it is going to come from as minorities increase in this population but are severely under-represented in health science research.

I would be happy to respond to any questions.

Senator MIKULSKI. Thank you very much, Dr. Satcher, for that testimony and the special insight that you bring. I just have a few questions and will then turn to my fellow panelists.

Dr. Satcher, could you explain what an "emerging center of excellence" means, and does this apply only to minority institutions?

Dr. SATCHER. No, I don't think it has to apply only to minority institutions. Our definition of centers of emerging excellence in biomedical research, however, does relate to the fact that there are some institutions that have had special barriers because of their missions, in terms of focusing on the under-representation of minorities in health science and having special programs geared toward solving those problems, but also institutions that have provided special access to health services in environments where large numbers and groups of people have had difficulty receiving health services.

So there are some special historical backgrounds related to these institutions and their missions, and despite that fact, they, in fact, are moving toward excellence in research. They have plans for research, they have demonstrated commitment to develop strength in research, and they have demonstrated a commitment and a capacity to impact upon a national problem, in this case, the under-representation of blacks and other minorities and the health status gap which I mentioned.

Senator MIKULSKI. Doctor, does the requirement of a 50 percent match place minority institutions or historically black institutions at a disadvantage?

Dr. SATCHER. Oh, I think it does, and we discussed that during the study group. I think there needs to be some flexibility in terms of match.

I think it is very clear that some institutions are in a much better position to match because of the history of their support from NIH, and I think we should be very clear about that. There are some institutions that, for the last 30 or 40 years, have, in essence, been developed because of their support from NIH and the indirect costs related to their support. They are in a much better position to match any kind of grant than other institutions that have not had the same access to NIH support or even publicly-funded facilities.

In 1982, for example, it was clearly pointed out in the case of Meharry Medical College, that Meharry had been excluded from publicly-funded facilities in Nashville—the VA and Nashville General Hospital—and primarily because of race. That was history, but that history is still impacting upon the institutions.

So I think it is definitely true that as we look at the situation today, there has to be some flexibility as we try to provide opportunities for institutions of emerging excellence.

Senator MIKULSKI. Thank you. What you are saying, Doctor, is that what appears to look like competition on an even playing field is not, in fact, an even playing field.

Dr. SATCHER. Exactly.

Senator MIKULSKI. We would welcome from the Association of Minority Health Professions Schools any recommendations to deal with that particular issue, because we know you need facilities, and you need all the help that you can get in generating those facilities.

As I understand, the Association of Minority Health Professions Schools does not have big endowments; it is a school that often has students that carry a heavy debt in order to be able to come to the school. When they graduate, they are very often deeply in debt, and just the ability to pay off their debt, enter their profession and get on with their lives doesn't necessarily mean they can come back and give you a new wing.

Dr. SATCHER. Exactly. And despite all of that, we feel very strongly that we make an outstanding contribution to this Nation and its needs; and it is on that basis that we consider ourselves institutions of emerging excellence.

Senator MIKULSKI. Yes, and we do, too. And we would welcome any thoughts you have on that matching problem.

Dr. SATCHER. Thank you very much.

Senator MIKULSKI. I am not going to ask you any more questions, but you heard the rather spirited discussion on work force needs. One of the concerns I have is that as loans and grants are shrinking, that it should not only be children whose parents have means to be able to seek education in the health professions. The great thing about our country, at least coming now into fruition, is that intellectual ability, compassion, dedication, is not rooted in class, it is not rooted in gender, and it is not rooted in race. But we want to make sure there are no barriers in participation.

Therefore, as we look at these work force needs, the student indebtedness, the ability for you to retain faculty, we would welcome ideas that you would have on dealing with this, and perhaps some type of public service commitment—we know we wiped out the Health Service Corps—but some type of temporary, time-limited public service commitment to reduce debt are the ideas that this Senator is particularly searching for, and we would really welcome from your profession ideas on that.

Dr. SATCHER. We would love to do that because, I think as you know, the National Health Service Corps was very important to institutions like Meharry, because more than half of our students were on National Health Service Corps scholarships. And since most of our students go to underserved communities anyway, it was an excellent opportunity for support for those students.

So we would welcome that kind of opportunity.

Senator MIKULSKI. Well, we welcomed your students to the Baltimore area, the graduates of Howard University who serve and are now practicing clinicians in part of the Mayor Schmoke advisory

team. We know the contribution you have made, and we look forward to your continued not only contribution, but your advice.

Dr. SATCHER. Thank you very much.

[The prepared statement of Dr. Satcher and responses to questions submitted to him follow:]

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TESTIMONY OF

DAVID SATCHER, M.D., PH.D.
PRESIDENT
MEHARRY MEDICAL COLLEGE

ON BEHALF OF THE

ASSOCIATION OF MINORITY HEALTH PROFESSIONS SCHOOLS

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

CONCERNING

REAUTHORIZATION OF THE
NATIONAL INSTITUTES OF HEALTH

ON

MARCH 29, 1988

Mr. Chairman and members of the Committee, I am very pleased to appear before you today to discuss the Congressional Reauthorization for the National Institutes of Health. It is very critical, in our view to maintain a strong federal commitment to biomedical research through the NIH and the investigators and institutions supported by this vital federal initiative. I would especially like to focus my remarks on the general research facility construction authorization that has been missing for several years.

Today, I am representing the Association of Minority Health Professions Schools, which is comprised of, with the exception of Howard University (which receives significant direct federal appropriations), all of the Black health professions schools in the nation. The eight institutions of the Association are the Meharry Medical and Dental Schools in Nashville, Tennessee; the Morehouse School of Medicine in Atlanta, Georgia; the Charles R. Drew Postgraduate Medical School in Los Angeles, California; the Tuskegee University School of Veterinary Medicine in Tuskegee, Alabama; the Texas Southern University College of Pharmacy and Health Sciences in Houston, Texas; the Xavier University College of Pharmacy in New Orleans, Louisiana; and the Florida A&M University College of Pharmacy in Tallahassee, Florida.

Our schools have trained 40% of all Black physicians and dentists in the nation, 50% of all Black pharmacists in the

nation, and 75% of the nation's Black veterinarians. Because our institutions have made such a significant contribution in training minorities in the health professions, many consider these schools a national resource.

Mr. Chairman, your Committee has played a very significant leadership role in insuring that adequate resources are provided to the federal programs of great concern to our Association, and we want you to know that we very deeply appreciate every consideration you and your magnificent Committee staff have given to these programs.

Minority Research

Now more than ever before, the institutions of our Association have begun to participate more heavily in biomedical research activities through the National Institutes of Health and other federal agencies. Many of our schools have made significant advances in the development of our research infrastructure and investigational capabilities. The Research Centers at Minority Institutions Program supported by NIH has proven a very valuable mechanism in the continued development of our institutional research capability, especially as it relates to studying diseases and health status factors that are more relevant to blacks than the general population.

In October, 1985, then Secretary of the Department of Health

and Human Services Margaret Heckler, released the Secretary's Task Force Report on Black and Minority Health. This report brought many sobering statistics to light. A black infant is twice as likely to die as is a white infant. Adjusted for age and sex, 60,000 excess deaths occur among blacks each year than do whites. Also, the report confirmed that blacks suffer a greater incidence of hypertension, diabetes, heart disease and some types of cancer. Among the recommendations made by the Task Force Report was that there should be a comprehensive effort to accelerate the development of the research infrastructure of institutions that train a significant number of minority health professionals. The thrust of this would be to assist in the development and training of black researchers and faculty to enhance the capability of these individuals and institutions to impact upon diseases that disproportionately affect blacks and other minorities. By doing so it is believed that these individuals and institutions will be able to develop the medical technology and expertise to close the critical health status gap among blacks and other minorities when compared to whites.

We view the underrepresentation of Blacks and other minorities in health sciences research, as a national problem of major concern. Despite the fact that Blacks represent approximately 12% of the U.S. population, less than 2% of the biomedical scientists in this country are Black, and similar statistics apply to the other sciences.[1] In recent years,

we have witnessed even a further decline. Since 1975, Meharry's School of Graduate Studies and Research has graduated more than 10% of all of the Blacks who have received doctorates in the biomedical sciences. Such an accomplishment, which represents a disproportionate contribution on the part of Meharry Medical College, has required special sensitivity, special recruitment expertise, special support programs and a special concern for major problems facing the nation today. As we look to the future and the growing representation of minorities in our population, it is critical that we maintain the strength of institutions that have targeted the underrepresentation of minorities in health sciences research for support and development.

Extramural Biomedical Research Facilities

Among the proposals being considered in the NIH reauthorization is a general facility construction authorization that has been missing for years. The state of biomedical research facilities in this nation is not good, and we support the development of a well thought out authorization for extramural biomedical research facility construction.

Just a few weeks ago, I, and others here today, participated in a Study Group on Extramural Research Facilities Construction sponsored by NIH and held at the National Library of Medicine.

Several trends were noted by the NIH Study Group that

substantiates the need for an improved focus on facilities. They are:

1) Considerable growth in scientific knowledge itself, with concommitant expectations for continued expansion of the knowledge base;
2) Rapidly developing scientific technologies and opportunities with attending expanded equipment needs and the facilities to contain them;
3) Increased special facilities construction requirements to comply with chemohazard and biohazard regulations;
4) Increased needs to support laboratory animal facility space and resources; and
5) The general problem of aging facilities - that is, a back-log of repairs, replacements and renovations.

The problem of facilities for the schools in our Association is not unlike many of the other challenges we face in our year-to-year operation. The collective missions of our institutions to train disadvantaged individuals to serve in underserved areas is a challenge to institutional financial stability. Because of that mission our institutions fall behind in the entire realm of research infrastructure -- from our research faculty, to instrumentation, to facilities. However, based on our past accomplishments with meager resources, we feel confident that we could make a significant contribution if these facilities and other support were provided. Particularly in

terms of studying diseases and health conditions that disproportionately affect Blacks and other minorities, our schools and the health care facilities associated with our schools are in the most appropriate settings to have a great impact.

The Association of Minority Health Professions Schools recognizes the importance of a federal facility construction system that utilizes peer review based on institutional capabilities, track record, and scientific merit. We also recognize and urge that some federal resources be awarded to institutions based on the health status needs of our nation, and the needs and capabilities of the institutions that can have the greatest impact on addressing those needs. The historically Black health professions schools in this nation have an emerging excellence and capability to train faculty, and study diseases that disproportionately affect minorities and we believe that when considering Federal facility renovation and construction resources, criteria should be developed that recognize these important unique capabilities.

Funding of construction for research facilities to eligible institutions that demonstrate emerging excellence in biomedical and behavioral research could be considered under the following criteria:

A. An institution that carries out research and training programs that have a special relevance to a problem, concern, or unmet need of the United States.

B. An institution that has already demonstrated a commitment to enhancing and expanding its research productivity.

C. An institution that has been productive in research or research training in the face of significant challenges such as a disproportionate role in impacting the underrepresentation of minorities in health science careers or the health status disparity of a large segment of the population.

D. An institution that has a plan for research advancement, and the ability to carry out such a plan.

Mr. Chairman, thank you for the opportunity to present the views and recommendations of the Association of Minority Health Professions Schools. Again, we appreciate the support your Committee has demonstrated to the programs supported by our Association. I am pleased to respond to any questions you may have.

MEHARRY MEDICAL COLLEGE
OFFICE OF THE PRESIDENT

April 12, 1988

Senator Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, DC 20510

Dear Senator Kennedy:

I am responding to your questions derived from the hearing relative to the reauthorization of the National Institutes of Health.

Question 1

In your opinion, is the line item funding in this bill adequate for facilites construction?

I do not believe the line item funding is presently adequate for facilities construction, however, I am also aware of the fact that we do not yet have accurate or complete data on the needs relative to facilties construction. Therefore, I am of the opinion that what is needed is at least a two-year evaluation period in which money is made available and institutions are asked to apply based on their level of need for construction. This process will allow us to get a better picture of what the needs actually are in the nation for facilities construction. Based on the data already available to us from the National Science Foundation studies and others, the need is greater than it is now being projected.

Question 2

In general, are the mandatory administrative requirements under current law and new specifications proposed in the legislation being considred today too restrictive?

In general, I do not feel that the mandatory administrative requirements under current law or the new specification proposed are too restrictive.

1005 D. B. TODD BOULEVARD • NASHVILLE, TENNESSEE 37208 • TELEPHONE 615-327-6904/6905

Question 3

What do you think should be the appropriate roles of Congress and the scientific community, respectively, in allocating resources amongst different areas of scientific research?

I basically feel that the peer review process in which scientific merit is evaluated by representatives from the scientific community is the ideal approach. However, it is critical that we understand that the peer review process is not a perfect process and that it needs to be carefully monitored. It is, therefore, in my opinion, the role of Congress to monitor the outcome of the peer review process. Where it is obvious that the outcome is not fair all segments of our society, then it is the responsibility of Congress to intervene, to apply pressure where it is needed in order to get the process back on track.

Sincerely,

David Satcher, M.D., Ph.D.
President

DS/vsd

MEHARRY MEDICAL COLLEGE
OFFICE OF THE PRESIDENT

April 25, 1988

Sen. Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Sen. Kennedy:

Please forgive my delay in responding to the additional questions submitted for my testimony before your Committee.

I am pleased to respond to the following questions:

1) **What does "emerging centers of excellence" mean? Does this only apply to minority institutions?**

The concept of emerging Centers of Excellence is intended to apply to institutions that have a special relevance to a national need for more health research manpower. As developed within the Committee, this concept applied specifically to institutions that have educated/trained a disproportionately large percentage of Blacks and other minorities who are health scientists in the country today.

In addition to this special relevance or commitment, these institutions also have a commitment to expanding and upgrading their research, with the understanding that it will directly impact minority manpower for research careers. Thus, emerging excellence implies a special mission or relevance and a commitment for expanding the research quality and base at an institution.

While in our discussion, the focus was on minority institutions, conceivably this could apply to other institutions that, for some reason, met these qualifications.

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2) **Given that minority institutions have been held back and been placed at a disadvantage in conducting biomedical research, how will a facilities program address those needs? Are facilities needs limiting research at minority institutions?**

Certainly, one of the weight-limiting factors in the development of research at minority institutions is the availability of the appropriate facilities. The facilities program would, in fact, expedite the development of research at minority institutions.

There are several examples of minority institutions that have implemented the research programs but have been limited by the fact that construction funds have not been available as well as funds for specialized equipment and other facilities. Thus, facilities needs are definitely limiting research at minority institutions. In some cases, the need is for revitalization or renovation. To be specific, Meharry Medical College has renovation needs that exceed $10 million, many of them in research-potential areas.

3) **Does the requirement of a 50 percent match place minority institutions at a disadvantage?**

Without question, minority institutions are placed at a disadvantage by the 50% matching requirement. Institutions that do not have large endowments or institutions that do not have a history of getting major funding from NIH and related sources with their associated indirect cost, are not in as good a position to match funds as other institutions.

It is our hope that the matching requirement will have the necessary flexibility to assure that we are dealing with a "level playing field."

In addition, I will respond to question #4 listed under your set of questions for Panel 2. The question states:

**Dr. Satcher, do you feel that the criteria in your testimony statement regarding eligible institutions that demonstrate emerging excellence in biomedical and behavioral research should be the only criteria, or is it a minimum set of criteria?**

It was our intent that these criteria would be looked at in conjunction with other criteria defined for eligibility for research facilities construction.

Question #4 (cont'd)

Certainly, every institution applying for these funds should have a definite commitment and a plan for research development. By the same token, an institution that is already engaged in research infrastructure development or research relevant to the needs of a special under-represented or underserved population should also be given special consideration.

Sincerely,

David Satcher, M.D., Ph.D.
President

DS/jsn

21/65

Senator MIKULSKI. We are now going to move on to our last panel on research and areas of promise. We would like Dr. John Ultmann, the Chairman of the National Coalition for Cancer Research, to come forward; Dr. Bruce Gans, Chairman of the Department of Physical Medicine and Rehabilitation at Tufts; Marlee Matlin, an actress from California, on communication disorders research, and Dr. Bruce Gantz, Professor of Otolaryngology at the University of Iowa, to come forward, please.

Gentlemen, we welcome you, and as you can imagine, your cotestifier, Ms. Matlin, is now communicating with Senator Harkin.

We are going to go ahead. Dr. Ultmann, we welcome your testimony. You represent the National Coalition for Cancer Research, and we welcome your ideas on cancer research. But I noticed from both you, Dr. Ultmann, and you, Dr. Gans, when I was raising some of those work force questions, this is a spot-on problem not only at NIH, obviously, but out in the field at academic research institutes.

So again, we welcome the testimony you are about to present, and feel free if you want to add a dash of work force.

Dr. Ultmann.

**STATEMENTS OF DR. JOHN ULTMANN, CHAIRMAN, NATIONAL COALITION FOR CANCER RESEARCH, CHICAGO, IL; AND DR. BRUCE GANS, CHAIRMAN, DEPARTMENT OF PHYSICAL MEDICINE AND REHABILITATION, TUFTS NEW ENGLAND MEDICAL CENTER, MEDFORD, MA, ON BEHALF OF AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION AND THE AMERICAN CONGRESS OF REHABILITATION MEDICINE**

Dr. ULTMANN. Good afternoon, Madam Chairwoman.

I am Dr. John Ultmann, Professor of Medicine and Director of the Cancer Research Center at the University of Chicago. As a volunteer, I serve as Chairman of the National Coalition for Cancer Research.

The National Coalition represents over 65,000 cancer researchers, physicians and nurses, 325 cancer hospitals, centers and clinics, and 57 cancer research centers. I thank you for the opportunity to appear before this Committee in support of the special authorities of the National Cancer Act, which you have so wisely chosen to maintain and expand under the reauthorization of the National Institutes of Health.

The National Cancer Act and its subsequent amendments are among the most imaginative and fruitful pieces of legislation ever envisioned by the Congress. We in the cancer research community appreciate the role the Congress has played in developing the National Cancer Institute's special authorities. The Chairman of this Committee was a driving force behind making the National Cancer Act a reality.

The Act gives the NCI a mandate to support basic research and to develop and apply the results of that research. The special authorities include, amongst others, the bypass budget, a budget request based on scientific judgment with the advice of the National Cancer Advisory Board, sent directly to the President; the President's Cancer Panel, a three-member advisory body appointed by

the President; the Presidential appointment of the Director of the NCI and of the National Cancer Advisory Board; authority to establish special peer review groups; cancer research and demonstration centers, called cancer centers, and prevention and control programs, called cancer control, to provide mechanisms to translate research findings into clinical practice; authority to train clinicians and researchers; construction funds; special information dissemination responsibilities; and foreign research and training authority.

The Act was a masterful compromise by which the Congress and the Administration agreed to leave the NCI within the NIH community, rather than create an independent cancer agency reporting directly to the President.

However, given the Nation's commitment to an expedited cancer program, these special authorities were created as a means of assuring expeditious, innovative cancer programs capable of moving quickly and flexibly.

As you are aware, the National Coalition for Cancer Research has been urging the Congress to expand the special authorities of the NCI. I thank you and the Committee for supporting our recommendations.

I would like to focus now briefly on three specific areas—cancer control and prevention, mammography, and opportunities before us.

First, cancer prevention and control.

We have realized in the past two decades that basic cancer research is the foundation of rational cancer prevention efforts. The information that we have garnered has led us to understand that prevention and control of cancer will only become a reality as we learn more about how a cell becomes cancerous—what the sequence of events is that occurs, what the factors in our environment are which influence it, and what promotes the development of cancerous cells, and how we can intervene to slow or stop the process. This understanding has led us toward emphasizing and implementing prevention studies which involve dietary and lifestyle changes including smoking cessation and chemoprevention.

The Prevention and Control Programs are divided into several components, which I have outlined in the testimony, including prevention research, community oncology program, and cancer control science, amongst others.

We have established networks of these research programs, including: 57 cancer centers; cancer cooperative clinical trials which include 5,000 investigators; the Diet, Nutrition and Cancer Program, which supports over 38 prevention trials, which has been testing 600 agents; the Smoking, Tobacco and Cancer Program, which supports 57 prevention and cessation studies; and a comprehensive cancer information dissemination activities program.

The goal of the National Cancer Institute—and this is very important—reducing the death rate from cancer in this country by 50 percent by the year 2000—is predicated on implementing the principles that we have learned over the past several years from our prevention and control programs.

Now, briefly, a word about one type of cancer reduction, breast cancer and mammography.

As you know, breast cancer is the leading cancer in women, with an estimated 130,000 new cases and 41,000 deaths in 1987. It is responsible for more new cases of cancer among women than any other cancer.

The detection of breast cancer at an early stage strongly influences the success of subsequent treatment. And minimal breast cancers are nearly 100 percent curable when treated by surgery.

Mammography is the only sure detection technique, and it is a tragedy—yes, a tragedy—that more women are not benefitting from it.

The Coalition agrees with the NCI in saying that if mammography were applied comprehensively across the United States to women over 50, that it is probabley that mortality from breast cancer would decrease by 30 to 40 percent.

Now, just one word on research facilities. Considerable has been said before.

The Coalition agrees with the NIH that there is a tremendous need to modernize our biomedical research laboratory and clinical research facilities. The Coalition supports the NCI bypass budget request for new resources to maximize our investment for construction renovation.

As you may know, this request for cancer facilities is based on a special study of construction needs sponsored by Dr. Armand Hammer and the American Cancer Society. We need additional research facilities, to upgrade facilities across the country to meet NIH containment standards and DHHS standards for animal care, and we particularly urge that NCI be permitted to renovate existing intramural laboratory areas for cancer detection and diagnosis and upgrading existing laboratories on interleukins and lymphokines for Dr. Rosenberg and others.

Speaking on behalf of the Coalition, we applaud the Senate Labor and Human Resources Committee's interest in giving more construction authority to the NIH. We do, however, believe that the NCI's own construction authority should not be diminished.

The future holds great promise, Madam Chairman. Scientific discoveries are coming at an unprecedented rate, and the NCI has built the network necessary to translate and apply them. By our working together and by our continued efforts in both the public and private sectors, we will sooner, rather than later, fulfill the mission of the National Cancer Institute in conquering disease and disability as a result of cancer.

This bill as well as your ardent support has brought us closer to obtaining this goal. On behalf of the Coalition, I thank you for your support.

This concludes my formal testimony. I will be happy to answer questions.

[The prepared statement of Dr. Ultmann and responses to questions submitted to him follow:]

THE NATIONAL COALITION FOR CANCER RESEARCH

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Executive Director
Mrs. Albert D. Lasker
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Robert V.P. Hutter, M.D.
Thos W. Shingleton, M.D.

Statement of

DR. JOHN E. ULTMANN, M.D.

Professor of Medicine and

Director, Cancer Research Center,

University of Chicago

CHAIRMAN, NATIONAL COALITION FOR CANCER RESEARCH

before the

Senate Labor and Human Resources Committee

on behalf of the

Reauthorization of the National Cancer Act

March 29, 1988

c/o The University of Chicago Cancer Research Center
5841 S. Maryland Avenue, Box 444 - Chicago, IL 60637
(312) 702-6180

Good afternoon Madam Chairwoman and distinguished members of the Committee. I am Dr. John E. Ultmann, Professor of Medicine, and Director of the Cancer Research Center at the University of Chicago. As a volunteer I serve as Chairman of the National Coalition for Cancer Research.

The National Coalition for Cancer Research is made up of nearly every cancer research, cancer care and lay group in this country representing over 65,000 cancer researchers, physicians and nurses, 325 cancer hospitals, centers and clinics, and 60 cancer research centers. On behalf of these individuals, I thank you for the opportunity to appear before the Committee in support of the special authorities of the National Cancer Act which you have so wisely chosen to maintain and expand under the the Reauthorization of the National Institutes of Health.

The National Cancer Act and its subsequent amendments are among the most imaginative and fruitful pieces of legislation ever envisioned by the Congress. We in the cancer community appreciate the role the Congress has played in developing the National Cancer Institutes (NCI) special authorities. There is absolutely no doubt in my mind that we would not have made the progress we made against cancer, if it were not for the special legislative authorities provided by the Congress. The Chairman of this Committee was a driving force behind making the National Cancer Act a reality.

The Act gives the NCI a dual mandate to support basic research and to develop and apply the results of that research. Some of the special authorities include:

* the By-Pass Budget, a budget request, based on scientific judgement with the advice of the National Cancer Advisory Board, sent directly to the President for review and transmission to Congress that cannot be modified at any level of bureaucracy;

* the President's Cancer Panel, a three-member advisory body appointed by the President and responsible for bringing any delays or blockages in the system to his attention;

* Presidential appointment of the Director, NCI and the National Cancer Advisory Board, demonstrating to the American public the Nation's commitment to cancer research;

* authority to establish special peer review groups to evaluate scientific merit of research applications;

* Cancer Research and Demonstration Centers (Cancer Centers) and Prevention and Control Programs (Cancer Control) to provide a mechanism to translate research findings into clinical practice;

* authority to train clinicians and researchers to maintain a supply of trained experts to continue cancer research efforts in the future;

* construction funds to upgrade cancer research, treatment and control programs at academic research and medical institutions throughout the country;

* special information dissemination responsibilities which hasten the transfer of new information to physicians, patients, and the public; and,

* foreign research and training authority to expedite our understanding of cancer from a worldwide perspective.

The Act was the result of a masterful compromise by which the Congress and the Administration agreed to leave the NCI within the NIH community, rather than create an independent cancer agency reporting directly to the President. However, given the Nation's commitment to an expedited cancer program, these special authorities were created as a means of assuring an expeditious, innovative cancer program capable of moving quickly and flexibly.

As you are aware, the Coalition has been urging the Congress to expand the special authorities of the National Cancer Institute in the reauthorization of this legislation. May I take

this opportunity to thank you and the other members of the Committee for supporting our recommendations and including them in the Committee's bill.

I would like to focus my testimony in three specific areas: cancer control and prevention, mammography and it's role in detecting and managing breast cancer, and the bright opportunities that we have for the future.

CANCER PREVENTION AND CONTROL EFFORTS

Cancer is older than man himself. However, truly great progress against this dread disease has only occurred in the past few decades and has accelerated in the 17 years since the passage of the National Cancer Act. What we have realized in the past two decades is that basic cancer research is the foundation of our cancer prevention efforts.

The information that we have garnered has led us to understand that prevention and control of cancer will only become a reality as we learn more about how a cell becomes cancerous--or malignant, what the sequence of events is that occurs during this process, what factors in our environment influence this process, what promotes the development of cancerous cells and how we can intervene to slow or stop the process. This understanding has led us toward emphasizing and implementing prevention and intervention studies which involve dietary and lifestyle changes

-- including smoking cessation and chemoprevention. We have realized that for the large part we just cannot protect people from the environment they live in. Rather, we need to protect people by incorporating into their lifestyle the factors necessary to minimize or eradicate their cancer risk.

The Cancer Prevention and Control Programs supported by the National Cancer Institute conduct a broad spectrum of applied research initiatives. The program focuses on intervention research to validate and evaluate prevention programs related to diet, chemoprevention and smoking cessation as well as interventions to improve the public's understanding about cancer and how to control this disease.

The Prevention and Control Programs is divided into several research components.

* **Cancer Prevention Research** to evaluate the role of diet and dietary components in the cause and prevention of cancer

* **Community Oncology Program** to improve the effectiveness of cancer detection, treatment and rehabilitation

* **Cancer Control Science** which focuses on intervention research to develop methods for applying research findings.

Our cancer prevention efforts rely heavily on the NCI

network to carry out these research programs and implement the results of its research. This network includes:

* 57 Cancer Centers

* a network of cancer cooperative clinical trials which include over 5000 individual clinical investigators

* The Diet, Nutrition and Cancer Program which supports over 38 chemoprevention trials and has tested over 600 agents with hope of identifying the most promising dietary agents to reduce cancer mortality and morbidity

* Smoking, Tobacco and Cancer Program which supports 57 prevention and cessation studies affecting over 10 million people in the United States

* comprehensive cancer information dissemination activities, including the NCI Cancer Prevention Awareness Program which is exempt from layers of bureaucratic review and delay.

The goal of the National Cancer Institute -- reducing the death rate from cancer in this country by 50% by the year 2000-- is predicated on implementing the principles that we have learned over the past several years from our prevention and control programs.

**BREAST CANCER AND MAMMOGRAPHY**

As you know, breast cancer is one of the leading causes of cancer in women, with an estimated 130,000 new cases and 41,000 deaths in 1987. It is responsible for more new cases of cancer among women than any other cancer and it also is the leading cause of cancer death among American women. In fact, one out of every 10 women in the United States is expected to have breast cancer some time in her life.

The detection of breast cancer at an early state strongly influences the success of subsequent treatment. Minimal breast cancers are nearly 100 percent curable when treated by surgery, including lumpectomy, regardless of whether a woman receives radiation or not. Many people do not realize that minimal cancer cannot be discovered by the women or her physician using physical examination only because of their small size. Mammography is the only sure detection technique, and it is a tragedy that more women are not benefitting from it.

The Coalition agrees with the NCI in saying that if mammography were applied comprehensively across the United States to women over 40, that it is probable that mortality from breast cancer would decrease by 30 to 40 percent.

**RESEARCH FACILITIES**

The Coalition also agrees with the NIH that there is a

tremendous need to modernize our basic biomedical laboratory and clinical research facilities in order that we can continue to be in the forefront of international biomedical research. I can honestly tell you that even the most brilliant of scientists must work in state-of-the-art facilities to make the maximum contribution to knowledge of which he or she is capable.

As you know the Congress had the foresight to provide the National Cancer Institute with the authority to award construction grants in 1974 when the National Cancer Act was reauthorized. This program has been a life-saver for the cancer and biomedical research community, although I must acknowledge that the resources available to this program have been less than adequate over the last several years. It is a severe problem that none were provided for FY 1988. The Coalition supports the NCI's By-Pass Budget request for new resources to maximize our investment for construction and renovation projects. As you may know, this request was based on a study of construction needs sponsored by Dr. Armand Hammer and the American Cancer Society. We need to

* build additional facilities having primary emphasis on cell surface and cell behavior studies, and on understanding metabolic pathways;

* build new animal facilities for biohazard containment required for DNA studies with mammalian cell, and renovate

existing facilities for research involving active antitumor agents and monoclonal antibodies;

* renovate existing laboratory areas for biohazard containment studies involving potent chemical carcinogens;

* upgrade many facilities across the country to meet NIH containment standards and DHHS standards for animal care; and,

* at the NCI renovate existing clinical laboratory areas for cancer detection and diagnosis and upgrade existing laboratory areas for research on interleukins and lymphokines.

Speaking on behalf of the Coalition, we applaud the Senate Labor and Human Resource Committee's interest in giving more construction authority to the NIH; we do, however, believe, that the NCI's own construction authority with needed resources will continue to be essential to the cancer research community.

The future holds great promise. Scientific discoveries are coming at an unprecedented rate and the NCI has built the network necessary to translate and apply them. By our working together and by our continued efforts in both the public and private sectors, we will sooner -- rather than later -- fulfill the mission of the National Cancer Institute in conquering disease

and disability as a result of cancer. This bill as well as your ardent support has brought us closer to obtaining this goal. On behalf of the Coalition, I thank you for your support.

This concludes by formal testimony. I will be happy to answer any questions you may have.

THE NATIONAL COALITION FOR CANCER RESEARCH

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Chairman

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THE SOCIETY OF SURGICAL ONCOLOGY, INC.
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William W. Shingleton, M.D.

April 28, 1988

TO: Senator Edward M. Kennedy
Chairman, Senate Labor and Human Resources Committee

FROM: Dr. John Ultmann
Chairman, National Coalition for Cancer Research

SUBJECT: Questions for the Record from the Hearing on the National Institutes of Health Reauthorization

Enclosed are my responses to the questions which you forwarded to me on April 4 and 7, 1988 in follow up to the hearing recently held before the Labor and Human Resources Committee on the reauthorization of the National Institutes of Health.

Once again, I thank you and your staff for your efforts on the part of the National Institutes of Health and in particular the National Cancer Institute in the reauthorization process. Your support is greatly appreciated in the cancer community.

c/o The University of Chicago Cancer Research Center
5841 S. Maryland Avenue, Box 444 - Chicago, IL 60637
(312) 702-6180

**IS THE LINE ITEM FUNDING IN THIS BILL ADEQUATE FOR CANCER RESEARCH?**

The By-Pass Budget has recommended that funding levels of $2,080,000,000 for FY 1989 for cancer research and prevention and control programs. This budget is a needs budget and reflects the actual amounts necessary to fully support the programs, goals and priorities of the National Cancer Institute. This level of funding is recommended by scientific consultants to the NCI and endorsed by the National Cancer Advisory Board. However, given the budget resolution and the current funds available this fiscal year for research programs, we recognize that cancer programs will not be funded at this level.

S. 2222, the Reauthorization of the National Research Institutes, authorizes $1,587,000,000 for cancer prevention and control in FY 1989 and "such sums as necessary" for FY 1990 and 1991. The 1989 President's Request, which does not include funding for AIDS research, is $1,393,355,000 for cancer research and $74,646,000 for cancer prevention and control. The National Coalition for Cancer Research believes that S. 2222 more closely represents what is necessary for the National Cancer Institute to meet current obligations and to fund more of the vast array of scientific opportunities awaiting exploration.

The National Coalition for Cancer Research is particularly pleased that the Committee has included "such sums as necessary" in the outyears. We believe that this will allow for more flexibility on the part of the appropriations committee which is necessary in order that we can bring the NCI budget more closely in line with the NCI By-Pass Budget.

**WHAT DO YOU THINK SHOULD BE THE ROLES OF THE CONGRESS AND THE SCIENTIFIC COMMUNITY, RESPECTIVELY, IN ALLOCATING RESOURCES AMONG DIFFERENT AREAS OF SCIENTIFIC RESEARCH?**

I believe that both the Congress and the scientific community have important roles to play in deciding how to allocate resources among different areas of scientific research. The National Cancer Act and its subsequent amendments reflect the foresight of the Congress in authorizing the Director, NCI to establish advisory committees comprised of non-governmental experts to assist the NCI in program and policy decisions. Boards of Scientific Counselors advise the NCI divisions responsible for research in cancer biology, causation, prevention, detection, diagnosis, treatment and control as well as the Frederick Cancer Research Facility on program direction and initiatives. In addition, these individuals provide NCI with input on the best allocation of available resources.

The National Cancer Act also established the National Cancer Advisory Board with broad representation from the scientific community which advises on broad policy issues. The President's

Cancer Panel, which consists of exceptionally qualified advisors, two of whom must be distinguished scientists or physicians, is charged by the Act to monitor the overall cancer research program, reporting any delays or blockages to the President.

Thus, in the National Cancer Act the Congress laid the foundation for the scientific community to have input into resource allocation decisions and advise on scientific opportunities in cancer research.

Congress, through the authorization and appropriations processes, determines the level of resources for a particular area of scientific research. Once again, the National Cancer Act supports this process in that it mandates that the NCI prepare a By-Pass Budget, a needs budget based upon scientific opportunity, to assist them in determining the allocation of resources. The Coalition for Cancer Research believes that the By-Pass Budget incorporates the best judgement of the NCI and the scientific community in developing the priorities for cancer research. The Congress, which must deal with the numerous competing priorities, can utilize the By-Pass Budget as a reference point knowing that it reflects the best judgement available on the necessary resources for cancer research.

The Coalition believes that the National Cancer Act assures that cancer research as well as prevention and control is managed with the right mix of congressional oversight and input from the scientific community.

**WHAT IMPACT HAS THE NATIONAL CANCER ACT OF 1971 HAD ON CANCER RESEARCH, TREATMENT AND PREVENTION? HAVE THERE REALLY BEEN SIGNIFICANT ADVANCES IN TERMS OF INCREASING SURVIVAL RATES SINCE THAT ACT WAS PASSED?**

As a result of the National Cancer Act and its subsequent amendments, the National Cancer Program in this country is unmatched anywhere in the world. We have established a network of hospitals, cancer centers, trained investigators, communication programs and prevention and control programs throughout the United States.

Over the years, many advances have been made in cancer research. Yet to limit the impact of our National Cancer Program would be to ignore the contributions cancer research has made to other diseases -- especially AIDS. The foundation of basic research programs supported by the NCI have been heralded as the primary reason that we have learned so much about the AIDS virus in such a short period of time. It was the knowledge obtained from the NCI-supported research in molecular biology, virology, retrovirology and immunology over the past two decades which prepared us to analyze the complexity of the AIDS virus. Because of this foundation we are in a better position to develop drugs and vaccines which will ultimately control this epidemic.

In addition, some of the cancer specific accomplishments of the past 17 years include the following.

* Advances in our understanding of the genetics of cancer
* Advances in molecular biology which have allowed us to make gene products and study them in large quantities and uncover the presence and expression of a cascade of genes, called oncogenes, in cancer cells that appear to control the growth and differentiation of cancer cells
* Furthered our understanding of the sequence of molecular events involved in mobilizing the immune system to fight against cancer cells
* Characterization of the motility of cancer cells which is helping us to study closer the whole process of metastatic cancer
* Identified more fully known carcinogens to reduce on the job exposure as well as self-exposure

In keeping with the idiom, "a picture is worth a thousand words" I have also included a copy of our brochure, **Curing Cancer: Possible Mission.** On page 7 of this brochure, there is a chart which clearly and dramatically demonstrates the progress we have made in our fight against cancer. I hope that you will include this brochure as part of my response.

**IN THE PREVENTION AREA, THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE HAS BEEN QUITE SUCCESSFUL IN EDUCATION AND SCREENING EFFORTS WHICH HAVE HAD A DRAMATIC IMPACT ON LOWERING THE DEATH RATE FROM CORONARY ARTERY DISEASE. DOES NCI HAVE COMPARABLE PROGRAMS? ARE THE MESSAGES REACHING THE PUBLIC? IS ENOUGH BEING DONE IN THIS AREA?**

The National Cancer Act explicitly mandated that the NCI support cancer control efforts. These efforts allow us to link what we learn in the laboratory to prevention, detection and cancer control programs.

In fact, the NCI prevention and control programs actually provided the model for the 1977 NIH initiative to develop demonstration, education and technology transfer activities at the NIH. At the present time the NCI supports a number of cancer control programs which include:

* **Smoking, Tobacco and Cancer Program**
* **Chemoprevention Program**
* **Diet, Nutrition and Cancer Program**
* **Early Detection Program**
* **Community Clinical Oncology Program**
* **Cancer Control Science Program**

Funding for cancer prevention and control programs have always

been separate from the basic research dollars. In guiding the Cancer Prevention and Control Programs, the NCI have developed objectives for the year 2000 which provide a foundation of activities which will allow the NCI to reduce the number of cancer deaths by 50% by the year 2000. These goals (see attached) will be impossible to reach if funding for these programs is not in line with the recommendations of the By-Pass Budget.

Senator MIKULSKI. Thank you, Dr. Ultmann.

Unfortunately, this Senator has to leave. I have to go to a meeting on getting the asbestos out of schools, something I know you are keenly interested in.

But now, the Committee will be chaired by a very able Senator, Tom Harkin. I wanted to say something about him in chairing this hearing and the role he has played that he would be too modest to say about himself.

Senator Harkin chairs the Subcommittee on the Handicapped. He wants to prevent those barriers. He has really put his heart and soul into that subcommittee.

What is also particularly special to me, and I was touched the other day, when Senator Harkin met with a group of students from Gallaudet, on the issues of particular concern to them. And because of his own brother, who had a hearing impairment, Senator Harkin can speak sign language. And when the students from Gallaudet sat down, for the first time in their lives, they had a Senator that they could talk to who could understand them and a Senator who could talk back.

And I was so moved, because again, I believe there should be no barriers to participation. And this is a Senator who has demonstrated, whether it is working in Chile, or whether it is working for Gallaudet, or working for the handicapped, that he knows how to listen and then act. And I will tell you, I just love this guy and what he is doing here.

## STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN [presiding]. Thank you. You are very kind. Thank you very much, Senator Mikulski, for those kind words.

I would just add, however, that I took over this Subcommittee from a very caring Senator, who also took great care and concern for the Subcommittee on the Handicapped, and that was Senator Weicker, for whom I have the highest, highest respect. We have had a close working relationship, and I think the one thing that has really marked this special Subcommittee is that the staff have worked so well together. We truly have a dedicated staff—and I say that both on Senator Weicker's side and on my side—in dealing with these issues.

So if I get accolades, it is only because of the work that the staff does.

I would just ask unanimous consent at this point to enter a letter and some questions by Senator Quayle, in the record.

[The material referred to follows:]

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# United States Senate

WASHINGTON, DC 20510

COMMITTEES:
ARMED SERVICES
BUDGET
LABOR AND HUMAN RESOURCES

March 29, 1988

The Honorable Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
SD428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Chairman:

I regret that I cannot attend the hearing on Tuesday, March 29, on the subject of reauthorizing the National Institutes of Health. However, I would request that you submit the following questions on my behalf to the witnesses. Further, I would like the witnesses' responses to be included in the record of official proceedings of the hearings. I also would like to receive a copy of each of their responses.

Thank you in advance for your assistance.

Sincerely,

Dan Quayle
U.S. Senator

DQ/ewk

Enclosure

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QUESTIONS BY SENATOR QUAYLE

Questions for Panel III, Dr. Ultman

1. "In your opinion, is the line item funding in this bill adequate for cancer research?"

2. "In general, are the mandatory administrative requirements under current law and new specifications proposed in the legislation being considered today too restrictive?"

3. "What do you think should be the appropriate roles of Congress and the scientific community, respectively, in allocating resources amongst different areas of scientific research?"

Senator HARKIN. Dr. Ultmann, I just have one question I am going to ask you before we move on.

Have there really been any significant advances in terms of increasing survival rates since the National Cancer Act of 1971 was passed?

Dr. ULTMANN. Both the national health statistics on mortality, which are always a few years old, and in individual disease areas, would reflect the tremendous progress which has been made.

In addition, I think the statistics, which are a few years old, reflect treatment practices which do not yet show what can really be done under ideal conditions.

If you take a disease, for example, such as Hodgkin's Disease—in which I am an expert—the treatment has changed completely from the time when I was a young faculty member to the present. It has changed in terms of understanding the pathology of the disease, in staging it, in treatment with radiotherapy and in treatment with chemotherapy. The state of the art today has moved an illness which, when I was a medical student, killed 95 percent of the patients in five years to a situation where approximately 87 percent are disease-free and mostly cured at the end of five years.

Now, there are many other diseases, particularly in children but also in adults, that have been affected by modern research being translated into clinical practice. Unfortunately, our statistics do not totally reflect success. In the largest measure, it is due to our singular failure to cure lung cancer.

Unfortunately, this is a great handicap for us, because this disease is a dreadful killer of men and women. Approximately 130,000 Americans die of this disease. Ninety-five percent will die within two years.

Unfortunately, breast cancer, which I just spoke about, has a high incidence, but less than half of the patients die in any one year, is now outstripped in women by lung cancer deaths. Now, the reason the statistics have not shown improvement is twofold. One is the responsibility of physicians; we have not succeeded in curing it. But the main responsibility rests with every individual who continues to light up in the face of all the facts, which indicate that tobacco consumed by smoking or chewing is a health hazard leading to cancer.

So I think tremendous success has been made. We understand now more about the biology of cancer than we have ever understood before. And I would say that the solutions which are coming down the pike rapidly in AIDS would never have been possible if the molecular biology-genetics programs had not been in place in the NIH and in place at the National Cancer Institute and increased in the past 17 years by the National Cancer Act. I think there is tremendous progress.

Senator HARKIN. Thank you, Dr. Ultmann, and thank you for appearing here.

Next, we will turn to Dr. Bruce Gans of the American Academy of Physical Medicine and Rehabilitation. I have a copy of your statement; without objection, it will be made a part of the record. If you could please summarize it in five to seven minutes, I would be appreciative.

Dr. GANS. Thank you very much, Senator.

I have brought some visual aids to help illustrate some of the points. I would like to concentrate my remarks specifically on support for the legislation that has been proposed as part of this NIH Reauthorization Act, Title V, that would create the National Center for Rehabilitation Research in the NIH. This is activity we have been working toward that has the support of the Arthritis Foundation, the National Multiple Sclerosis Society, the Cystic Fibrosis Foundation, a number of other organizations, as well as the American Hospital Association.

Rehabilitation medicine is a branch of medical sciences that includes a number of specific diagnoses. We deal commonly with patients with neuromuscular diseases, a variety of medical illnesses, and a number of musculoskeletal disorders in particular.

We are as concerned with children who have congenital limb deficiencies as we are with young adults who have suffered from traumatic spinal cord injuries. We also care for elder citizens who have had strokes.

As you can see, our specialty knows no age boundaries. We are as concerned for children, people in their prime, and our senior citizens.

Whether that child has cerebral palsy, whether that adult has a traumatic brain injury, or whether it is a senior citizen afflicted with a degenerative neuromuscular disease such as amyoltropic lateral sclerosis, or ALS.

Rehabilitation medicine concerns itself more than just with disease. We are concerned with the impairments that are a consequence of disease. We are concerned even greater with the disability associated with those impairments, and ultimately, we are also vitally concerned with the handicap, the inability to perform social functions, because of these disabling disorders.

We are also concerned with the problems of disability that cut across a variety of specific diagnostic and specialty groups. For example, a patient with spinal cord injuries will need a variety of health professionals. He or she will need medical services, urologic surgical services, neurologic and neurosurgical services, orthopedic surgical services, and a variety of psychosocial services to improve his or her ability to function and return to normal lifestyle.

But rehabilitation medicine is the field of medicine that encompasses all aspects of these and takes care of the whole person.

From another point of view, rehabilitation is concerned with four major disability problems. We are concerned with weakness, which is usually expressed as paresis or paralysis; we are concerned with the loss of sensation of body parts; we are vitally concerned with the loss of body parts themselves, and we are especially concerned with spasticity. Spasticity is a final problem that is caused by a number of different neuromuscular disorders. Everything from cerebral palsy to multiple sclerosis, amyoltropic lateral sclerosis, head and spinal cord injuries and stroke result in this same problem.

So we are as concerned about the spasticity of a child who has suffered a head injury and is learning to walk again as we are with the spasticity associated with severe spinal cord injury, as in this child who is so highly and severely disabled that he even requires a ventilator, but was able to return home on a ventilator with rehabilitation services.

Medical rehabilitation research has accomplished a great deal in the past. We have had major advances in the systems of care; we have seen the development of spinal cord injury systems as regional centers of excellence; there are new initiatives that are now starting to create regional centers of excellence for traumatic brain injury rehabilitation.

Rehabilitation engineering has resulted in the development of customized computer-based devices that allow severely disabled cerebral palsy children to talk, using computer speech synthesis. We have seen advances in prosthetics and orthotics that allow the use of modern space-age materials to advance our ability to improve function and prevent deformities, such as this bracing and splinting material. And we have seen the advancement of our ability to take advantage of commercially available technologies and to apply them to the needs of disabled children so that this spinal cord injured child can communicate and write and do his homework on a personal computer.

But there are many more opportunities for research that are just at the forefront of our capacity. This is an example of research looking at whether personal computers and robotics systems can be used by disabled people to manipulate their environment under voice or switch control—a very promising area.

We are even seeing new ways to give people who are severely disabled the ability to control their environment. In this research, a television camera is observing the eye position of the subject, and he is looking at letters on a screen, and the computer is detecting what he is looking at merely by being aware of his eye position. This person can "talk", using a computer, while only moving his eyes.

The trick to this and many other areas of research is building our research training capacity for the future. Rehabilitation medicine has not attracted a highly sophisticated body of researchers. It does not have a superb track record in the past, and there are several reasons for this. One is that it is harder than most other medical and biomedical research because the problems are vastly greater, they are more difficult to quantitate, and they require sophisticated and somewhat different methodologic principles of research than are used in the traditional biomedical research communities.

We need to build a research capacity because we have not had the opportunity to do that, and research training is one of the key elements we are concerned for in this proposed legislation.

The future of rehabilitation research is great. We have a number of intriguing opportunities and unique capacity. We need a specialized, discrete program within the National Institutes of Health that can recognize the needs and opportunities for rehabilitation research that complement the existing programs of research in specific projects, that allow an understanding of the cross-cutting nature of rehabilitation research, that will give us the capacity to link the expertise and take advantage of the wonderful excellence

of scientific research that exists in the NIH and apply it to create cost-effective and exciting new opportunities for our disabled population.

Thank you.

[The prepared statement of Dr. Gans and responses to questions submitted to him follow:]

TESTIMONY OF

BRUCE GANS, M.D.

for

THE AMERICAN ACADEMY OF

PHYSICAL MEDICINE AND REHABILITATION

and

THE AMERICAN CONGRESS OF

REHABILITATION MEDICINE

Before

the

Senate Labor & Human

Resources Committee

on

March 29, 1988

Mr. Chairman:

I am Bruce Gans, M.D., a member of the American Academy of Physical Medicine and Rehabilitation (a medical specialty society representing the interests of 3,000 physicians and residents) and the American Congress of Rehabilitation Medicine (a multi-disciplinary professional society of 2,500 members involved in research and training) and Director of the Tufts New England Medical Center Rehabilitation Research and Training Center. I am testifying on behalf of the Academy and Congress in support of legislation which, among other things establishes a National Center for Medical Rehabilitation Research in the NIH. Legislation creating such a National Center is supported by many other organizations, including the Arthritis Foundation, the National Multiple Sclerosis Society, the Cystic Fibrosis Foundation, the Epilepsy Foundation, United Cerebral Palsy, the National Easter Seal Society, the American Spinal Injury Association, the American Academy of Orthopedic Surgeons, the National Association of Rehabilitation Facilities, the Academy and Congress, representing psychologists, nurses, physicians, physical therapists, occupational therapists, speech pathologists, counselors and social workers.

Rehabilitation medicine involves the diagnosis and treatment of physically disabled persons to minimize the disabling effects of disease or trauma and restore physical, as well as psychological, social and vocational function. The physically disabled with whom we work have neurological, muscular and

musculoskeletal disabilities such as stroke, arthritis, head injury, spinal cord injury, multiple sclerosis, cerebral palsy, amputations and congenital limb deficiencies such as spina bifida. Rehabilitation medicine therefore is involved with catastrophic illness. The disabled treated include all age groups and many individuals are covered by Medicare and Medicaid. 70% of Academy members are participating physicians in the Medicare program. We are concerned with assuring that severely disabled individuals regain their capability to walk, to communicate, to dress and eat independently, to engage in physical exercise, and most important, to return to work or home and independence. Our positive contributions to society are measured by the numbers of courageous disabled people of all ages who return to work or school or at least live independently.

Stroke research at the University of Washington, Seattle, established that an inpatient rehabilitation program for stroke patients resulted in 75% of patients living independently after a six month follow up even though over 60% had been institutionalized before the program. Comparable research has shown similar effectiveness regarding the managment of spinal cord injury with lessened hospital stays and much lower death rates. Initial hospital stays have been reduced by about 1/3 in a decade. Since World War II medical rehabilitation has been good business for society and this is true today more than ever.

The growing relevance of rehabilitation medicine is nowhere better exemplified than in the care of our increasingly aging population. T. Franklin Williams, M.D., currently Director of the National Institute on Aging, has written "The aim of rehabilitation to restore an individual to his or her former functional and environmental status or to maintain or maximize remaining function should be at the heart of all care for aging persons . . .".

Let me just provide you with some brief data on the numbers of severely disabled people and their potential cost to society if not rehabilitated effectively. About 500,000 Americans have strokes each year, and while 155,000 die, half at least are alive seven years later although often with impaired mobility, strength and communication ability. About 37 million people suffer from disabling arthritis at a cost to society of $9 million dollars. About a quarter of a million Americans have multiple sclerosis and the cost to society is great, estimated at $2 billion a year. 2 million Americans suffer from stroke and it is estimate that in 1987 the cost of stroke in lost productivity and health care costs was about $13 billion. Trauma is estimated to affect some 60 million Americans a year with 9 million being temporarily disabled and 340,000 permanently disabled. Head injury and spinal cord injury are the major examples of severe disability induced by trauma. The Institute of Medicine Report "Injury in America" (1985) indicates that injury is the leading cause of

disability with motor vehicle injuries alone resulting in a cost to society of $36 billion in 1980, second only to cancer. The Report indicates that 75,000 Americans a year sustain brain injuries resulting in long term disability and 6,000 each year are discharged from hospitals with spinal injury and either paraplegia or quadriplegia. Another recent Institute of Medicine study indicated that the total costs from disability for the under 64 population alone doubled from 1970 to 1982 and was $121 billion in 1982. Now it is probably $150 billion.

Medical rehabilitation can preserve the quality of life for patients and save our economy money. We face rapidly growing medical problems of dealing with the medical aspects of disability as our population ages and as we are capable of preserving life for people who a few years ago would not have survived. Medicine is doing great things in preserving life, but we must do much more to preserve life in which disabled people can function independently, live outside of institutions and enjoy a full life. Rehabilitation medicine is dedicated to those goals. But the effectiveness of every medical care system or specialty depends upon a rich scientific foundation. There are four major research areas in which new knowledge is essential and which are common to medical rehabilitation and to numerous physical disabilities: spasticity, weakness, sensory loss and limb loss. We in rehabilitation medicine must also know more about the basic reasons for the damage and degenerative effects

on the elements of central and peripheral nervous system which relate to disability from spinal injury, M.S., cerebral palsy and other conditions. We must increase our knowledge about the pathology of soft tissue, muscle and bone to effectively deal with disabling conditions. We need clinical and applied research on various treatment methods from electrical stimulation to exercise and medication. Research in rehabilitation medicine is primarily clinical or applied science but often also includes or leads to basic biomedical science regarding nerves, muscles, bone, skin, and various organ systems. In summary, we must have a well organized and funded research program in rehabilitation medicine and a stimulating research environment.

Medical rehabilitation research is, however, patient focused not disease focused. Ultimately we are concerned with the functional capacity and quality of life of our patients. Medical rehabilitation research is not research on the pathology of neurological disease, or musculoskeletal disorders or skin disease. Nor is it related only to a particular age group since all suffer from disability. Let me use the example of spinal cord injury. Rehabilitation medicine is concerned with the prevention of medical complications and the functional capacity of the disabled person. But that concern is not just for the renewed use of the neurological system. Research on neurological aspects alone is not sufficient. Our concern is also for the many severe complications of spinal cord injury such

as skin ulcers and urinary tract infections. Furthermore, we are providing better care in acute and rehabilitation medicine so spinal cord injured people in large numbers are surviving with fewer medical problems and will soon be aged and present unusual problems for the aging research community. A center for research at NIH is necessary to focus on the multiple disabling effects of various chronic diseases and traumatic disorders and to focus on the major common issues of medical rehabilitation involving spasticity, weakness, sensory loss and limb loss.

Let me list for you a few examples of the great need for further research in the medical rehabilitation field:

1) The National Research Council of the NAS "Injury in America" report places a major focus on the need for " a national effort to achieve appropriate emphasis on disability related basic and applied research and development". The report includes a summary of what is known and needed in rehabilitation research and I shall submit this for the record but the areas of need include medical research on pressure sores, preservation of spinal cord function, burns and soft tissue injury.

2) The Institute of Medicine, 1987, Study on Pain and Disability, recommended that "the Secretary of HHS take the lead in ensuring that a broad research initiative on pain and disability is undertaken within HHS". This recommendation includes in particular epidemiological studies to identify determinants of pain, and clinical studies on the effectiveness

of rehabilitation modalities to control pain. A Medical Rehabilitation Center at NIH is a perfect agency to take the lead in this badly needed effort, as well as the effort in medical rehabilitation research called for by "Injury in America".

3) Rehabilitation medicine has made gigantic strides in the past twenty years to develop quantitative methods to measure functional status of patients with physical disabilities. These measures are now available to provide excellent tests of the effectiveness of various medical treatment of neurological and musculoskeletal impairments.

4) The burgeoning field of transplantation will create an enormous demand for new knowledge about improving function of individuals with limb transplants. Similarly, the development of regeneration and spinal cord or brain transplants will correspondingly call for new knowledge as to the effectiveness and adaptability which these techniques will produce.

## Description of Legislation Proposed

We are proposing legislation to create a National Center for Rehabilitation Research in NIH.

### 1. The Goals

The legislation which is included in the Senate NIH Reauthorization bill and HR 4013 is intended to achieve a number of specific goals regarding medical rehabilitation:

1. the establishment of a Center as a focal point within NIH to assist in planning for and coordinating all medical rehabilitation research throughout NIH;

2. the development of a comprehensive research plan for medical rehabilitation research.

3. the stimulation of further research throughout NIH on medical rehabilitation by the existing Institutes.

4. the support of research on medical rehabilitation by the National Center which is not funded by the existing categorically related institutes: generic research programs such as research training; clinical research which is multi-faceted such as spinal cord management involving skin problems, urologic problems and neurologic problems; research regarding spasticity, weakness, sensory loss and limb loss.

5. better coordination of research activity in medical rehabilitation throughout the federal government; and

6. the enhancement of visibility and need for more research in rehabilitation generally.

2. How the Legislation Would Work

The Center would be responsible for staffing planning activities carried out by the Director of NIH. The bill calls for a research plan to be developed by the Director after being advised by the Center Director and a broad based consumer, scientific and agency advisory council. The plan would establish research priorities for the various NIH Institutes and agencies and seek to assure the development of a coordinated NIH program. The plan shall be reviewed annually and should be the governing element of a comprehensive NIH research program in medical rehabilitation. The specific areas of research activity of the various agencies within NIH would be spelled out in the plan. Other federal agency officials would have input to the plan through the Advisory Council and coordination should be established in this way between federal agencies responsible for research in medical rehabilitation.

The Center would also be responsible for funding programs in medical rehabilitation which were identified in the plan as appropriate for the Center to support. The Center has a general mission to support research in all aspects of medical rehabilitation which includes matters related to musculoskeletal, neurologic, urologic, skin, and cardiopulmonary problems as well as problems of the aged and children. It would be well suited, therefore, to support priority research which was identified as

needed but not within the purview of a particular institute or not being supported because of that Institute's priorities (e.g. basic science as opposed to clinical science). Research training in the general field of medical rehabilitation is an area which the Center would necessarily be responsible for since it is a generic activity and no Institute is doing it. In addition, clinical research involving the management of many disabilities such as spinal cord injury, head injury, multiple sclerosis or cerebral palsy involve many different patient problems affecting different organ systems and should be analyzed in one clinical research setting. Even specific, areas of research such as spasticity control, the use of functional electrical stimulation in improving function might be undertaken by the Center because those areas were considered high priority, but the existing Institutes did not view them as priorities. The Advisory Council would review Center priorities to assure they were appropriate given consumer needs, other agency interests and scientific capability The Advisory Council is a coordination mechanism because of it's breadth.

The Center would also focus upon collaborative research opportunities with other NIH agencies such as the Aging Institute, the Child Health and Human Development Institute and the Nursing Research Center and other federal agencies such as NIDRR, the V.A., and NASA.

The Coordinating Committee within the NIH would focus upon assuring coordination of activity within NIH. Coordination of activity between NIH and other federal agencies would be the function of the Interagency Coordinating Committee set up under the Rehabilitation Act and cooperative agreements between agencies. Such coordination would be enhanced by the Advisory Council to the NIH Center.

3. What the Legislation Doesn't Do

This legislation does not transfer any funds from any other agency to NIH, nor does it transfer any funds from existing NIH Institutes to the Center. It simply authorizes a new program in NIH to enhance NIH planning, coordination and program development in the medical rehabilitation area.

What is proposed in HR 4013 and the Senate NIH Reauthorization bill is consistent with the criteria developed by the Institute of Medicine for new entities at NIH. The mission of the National Center for Medical Rehabilitation Research called for by this legislation is basic and clinical medical research, fully consistent with the mission of NIH. The Center would enhance the accountability, priority setting and management of medical rehabilitation programs in NIH because it establishes an agency responsible for these activities whereas

none exists now but is needed. While funding should be enhanced through the establishment of an NIH entity responsible for medical rehabilitation research, and while funding has been wholly adequate, funding is not so much the issue as a clear and appropriate focus within NIH for medical rehabilitation research. This focus must be in a new entity, separate from existing agencies in NIH, because the existing agencies are too narrowly focused on a disease area or age group. A separate entity is also essential to stimulate effective collaboration between agencies.

We urge that the legislation be enacted and thank this Committee and the sponsors for their leadership on this matter.

Injury in America
N.A.S. - 1985

TABLE 6-1 Status of and Deficits in Rehabilitation-Related Research

| Known or Available | Unknown/Needed |
|---|---|
| Control of disabling complications: Role of inactivity and immobility; effects of conventional treatment on cardiopulmonary-musculoskeletal metabolic and stress effects, including pressure sores and infection. | Understanding of how to provide effective prevention and treatment during active physical rehabilitation and after deinstitutionalization in habitat, work, and recreational settings; methods for individualizing reactivation, energy expenditure, use of protective and energy-conserving activities and devices, and pressure-relief systems. |
| Use of anticipatory management: Amputations; improving successful use of prosthetics; reconstructive microsurgical, macrosurgical, and plastic surgical and nonsurgical procedures for skeletal immobilization; functional mobility for self-care, environmental control, physical and occupational therapy. | Understanding of how to achieve wider use through demonstration models for educational revisions and postgraduate training; improved technology and assessment procedures for effectiveness and for innovations in procedures; biomaterials technology for transplantations, artificial joints, and internal instrumentation; improvement in structure, stability, function, and cost of care and cosmetic devices. |
| Techniques for prevention of contractures, muscular atrophy, and skeletal deformity: Available modular orthotic systems for hand, arm, back, and leg control and protection and use of residual controllable muscle strength. | Knowledge of mechanisms of tissue contractures, muscular atrophy, and joint fixation limiting residual motor power; control of bony demineralization with reduced strength and losses of living activities (from falls and transfer injuries); research on effectiveness of early activities of living and postural weight-bearing effects on collagen structure and function; utility of new types of temporary corrective splints for deforming forces, and use of functional electric stimulation. |
| Restoration of function and use of residua: Existence of hidden residual voluntary motor control and mechanisms for production of involuntary movement, spasticity, etc.; various surgical, microsurgical, and neurosurgical techniques; medical treatment, e.g., external and implanted electric stimulation to control spasticity and pacing ventilation and biofeedback techniques in neurotrauma treatment; pharmacologic and cognitive retraining systems and technologies for the brain-injured. | Means of selecting persons with potential to benefit; studies of comparative cost-effectiveness of alternative treatments; creation of model tertiary evaluation and treatment referral centers aimed at individualized selection and new treatments and technologies as well as at research, education, and dissemination of results to handicapped persons and professionals. |
| Devices and systems to replace missing functions: Sensory substitutes for deaf, blind, and deaf and blind; environmental control systems for paralyzed; vehicle control systems, safety designs for access and egress. | Development, testing, pilot production, and distribution; financing of devices and systems, both simple and complex, such as technology for reading and communication; affordable robotic systems and understanding of adaptive factors defining appropriate use of assistive devices and systems and long-term adaptations. |

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TABLE 6-1 (Continued)

| Known or Available | Unknown/Needed |
|---|---|
| Orthotic systems | New techniques to stabilize head and neck movements after injury during healing and to permit early activities. |
| Mobility systems | Less expensive powered wheelchairs; new seating and posture designs to minimize pressure sores. |
| Pressure sore control and prevention | Development of research results into widely available systems to prevent pressure sores; training centers for care personnel with wider use of audiovisual aids; self-management resource centers for handicapped persons (independent-living centers). |
| Self-care technology | New independent living to aid kitchen, bathing, and similar activities of daily life; self-care equipment usable by handicapped persons of all ages, including elderly. |
| Physical, environmental, and social attitudinal handicaps: Design standards for physical-barrier reduction and for transportation system access. | Development of performance standards to permit wider variation in workable solutions for homes, commercial buildings, and public transportation; further architectural research and development to simplify retrofitting of existing buildings. |
| Origin and reinforcement or diminution of social attitudes and behaviors | Sociologic and psychologic research with prospective designs and evaluation of alternative educational, informational, and behavioral modification research to reduce discrimination in education, job placement and job retention, recreational access, etc. |
| Service delivery system: Service delivery models and systems restricted primarily to spinal cord injury. | Uniform reporting systems; reporting of disability days from severe disabling injuries, as death and morbidity are reported; development and cost-effectiveness evaluation of tertiary rehabilitation treatment systems connected to trauma centers for management of brain-injured, brain- and spinal-cord-injured, and multiinjured persons. |
| Regional technology delivery systems | Establishment, operation, and evaluation of regional technology service centers for information dissemination, prescription, use training, maintenance, and follow-up; research and development for practical applications of high- and low-technological devices and systems for mobility, controls, self-care, environmental controls, communication, and sensory and movement substitutes. |

## ADVANCES IN REHABILITATION MEDICINE RESEARCH

- There has been a marked decrease in urinary tract complications following spinal cord injury. Kidney failure was the leading cause of death within the past 15-20 years. Fairly recent research has resulted in improved management of the paralyzed bladder and control of infection which in turn have led to improved survival rates. Renal deaths are now the third most common cause of death in persons living for many years; in persons injured during the last 15 years, renal deaths rank 13th. The causes of death of spinal cord injury patients are now approximating those of the non-spinal cord injured population.

- Improved methods of spinal cord injury care and management have reduced the initial hospital length of stay from 137 days in 1974 to 100 days in 1984. Research has helped to reduce secondary complications, improve medical care and rehabilitation and thereby improve the quality of life for spinal cord injured persons. Reduced lengths of hospitalization are also paralleled by a relative decrease in costs.

- Organized model systems of care, treating patients from the first day of injury through rehabilitation and follow-up, have reduced the initial length of hospital stay compared to non-organized fragmented health care services.

- The complications of blood clots following spinal cord injury have been reduced from 80% to 10% through new methods of prevention. This has also decreased the incidence of blood clots to the lungs which have been a fairly frequent cause of death following spinal cord injury.

- A Uniformed National Data System has been developed to scientifically measure physical function and impairment and monitor the quality of rehabilitation care. This system can be used to assess various methods of management and consequent functional improvement and determine the cost effectiveness of these methods.

- The feasibility of functional electrical stimulation to control the movement of paralyzed muscles of the arms and legs has now been demonstrated.

- Specific types of exercises for enhancing muscle strength, coordination, and the prevention of joint stiffness have been developed and applied to specific medical conditions.

- Long term studies of prognosis for functional outcome following catastrophic events such as trauma to the central nervous system or stroke have been completed. Vocational success following traumatic brain injury may be predictable in a rehabilitation setting and employment can be enhanced.

- Different patterns of language impairment have been demonstrated in stroke and traumatic brain injury and the natural course of recovery has been followed. Nonverbal communication devices have also been developed for persons without speech.

- Techniques for diagnosing and remediating visual perception defects in stroke patients have been developed and validated.

- There have been improvements in prosthetics (artificial arms and legs) for persons with congenital or traumatic amputations.

- Three dimensional techniques have been developed to map body parts and assist with the fitting of prostheses for amputated extremities.

- Clinical methods have also been developed and applied to biomechanical models to analyze human motion including walking and the use of the arms.

- Improved lightweight plastic orthoses (braces and splints) have been developed to improve patient function. This has included simplified powered and non-powered orthoses to assist paralyzed persons with self care activities include eating, grooming, hygiene, etc.

- There has also been improved mobility for the disabled person including electric wheelchairs, lightweight manual wheelchairs and hand controls for road and other vehicles.

- Improved control of spasticity following central nervous system injury has been possible through newer drugs, surgery and other therapeutic modalities.

- The prevention of pressure ulcers is more feasible through newer pressure measuring devices and the development of specialized seating techniques.

- Behavioral techniques for managing persons with chronic pain have been developed, validated and introduced into rehabilitation medicine practice.

- Systematic evidence has been provided documenting the value of physical therapy to increase ambulation in patients with multiple sclerosis.

- Transitional living programs have been developed to assist persons who have completed rehabilitation and need to return and adapt to community living.

Rehabilitation Medicine research deals primarily with neuromusculoskeletal disorders; however, many of the conditions treated, such as spinal cord injury and head injury, affect multiple organ systems which in turn affect the total health of the patient over a life span which may include infancy to aging.

## FUTURE NEEDS FOR REHABILITATION MEDICINE RESEARCH

The following is a list of examples of needed research in the field of rehabilitation medicine. This is certainly not an inclusive list.

1. The use and effectiveness of many therapeutic modalities currently being used in rehabilitation, i.e., biofeedback, therapeutic electricity, therapeutic exercise, heat, cold, splinting, casting, etc.

2. Prevention of complications following spinal cord injury which can be applied to many other conditions where there are central nervous system or neuromusculoskeletal impairments

3. The management of traumatic brain injury and methods to reduce long term physical impairments and disability

4. Neuropharmacology of traumatic brain injury

5. Functional electrical stimulation and its effectiveness in improving function

6. Methods to improve the long term function of persons receiving artificial joints and/or organ transplants

7. Additional methods to prevent skin complications, especially pressure ulcers

8. Increased basic science research which can be integrated into the field of rehabilitation medicine

9. Research manpower needs in rehabilitation medicine

## MAJOR CURRENT AREAS OF RESEARCH AND REHABILITATION

1. Brain injury
2. Spinal cord injury
3. Stroke
4. Electrophysiology
5. Muscle and nerve
6. Neuromuscular
7. Elderly
8. Prosthetics/Orthotics
9. Biomechanics
10. Functional outcomes
11. Quantifications of performance

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GANSTEST/

AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION

May 19, 1988

The Honorable Edward M. Kennedy
Chairman
Senate Labor and Human Resources Committee
315 Russell Senate Office Building
Washington, D.C. 20510-2101

Dear Senator Kennedy:

You have asked me a number of questions regarding the NIH re-authorizing legislation, and in particular about Title V of S.2222, creating a National Center for Medical Rehabilitation Research. The following are my answers for the record to the questions.

1. Is the line item in the legislation adequate for the needs of the National Center for Medical Rehabilitation Research?

The legislation has no specific line item budget authorization for the programs authorized under Title V. It is our assumption that some clarification would be helpful to the effect that the general authority in Section 301 of the Public Health Service Act for NIH programs would apply to programs of Title V. If this assumption is correct, then the method of providing for an authorization is certainly adequate since there is a general authorization provided under Section 301.

2. In general are the mandatory requirements in current law and the new specifications in S.2222 too restrictive?

We do not believe that current law, as amended by the provisions of Title V of S.2222 are too restrictive. Title V is intended to facilitate collaborative activity between the various agencies within NIH which undertake programs and projects in the field of medical rehabilitation. The provisions, therefore, do not restrict the abilities of existing agencies to undertake programs. The definition of medical rehabilitation is broad and therefore not restrictive. The National Center for Medical Rehabilitation Research has broad authority so it is not restricted, although its operations are intended to supplement existing NIH activity. The Advisory Council created by Section 486(F) includes representation from most all agencies with a role in medical rehabilitation research and that Advisory Council will participate in the development of

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a research plan to guide medical rehabilitation research activity throughout NIH. Thus, all relevant interest will have participation in a planning process designed to ensure collaboration and enhance flexibility.

3. What should be the relative roles of Congress in the scientific community in allocating resources among different areas of research?

We believe that Congress should play a major role in establishing priorities for the allocation of resources among the different areas of research. We think that the scientific community has an obligation to articulate areas of priority research to the Congress as part of the annual appropriations process. Obviously, the Executive Branch has that same opportunity and does so by submitting an annual budget request. We do not think that the Congress should necessarily establish specific project areas for research unless the evidence is very substantial that an important area is unfunded, but has substantial potential for positive results. Congress should be able to establish general areas of priority such as the area of medical rehabilitation research as defined in Title V.

4. Does the NIH currently support about $50 million in medical rehabilitation research and what could the National Center for Medical Rehabilitation Research support that is not covered by existing Institutes.

It is extremely difficult to determine how much money is being spent on medical rehabilitation research as defined in Title V of S.2222 because NIH does not specifically report on funding in that particular area of research. NIH reported that approximately $90 million was spent on research related to rehabilitation generally and more recently we have seen the figure $107 million for 1987. However, within those amounts are included all kinds of research activity related to mental retardation, blindness and deafness which are not defined as medical rehabilitation research under Title V. Medical rehabilitation research is defined as research regarding physical disabilities and particularly of the neurological, musculoskeletal and cardiopulmonary systems. The primary examples of research in this area involve research regarding spinal cord injury, multiple sclerosis, stroke, amputations, arthritis and head injury. It is our very rough estimate that only about $20 million was expended on medical rehabilitation research as defined in Title V of S.2222 in 1985 and that amount would not have increased since then since no new programs have been started. In some respects, it is fair to say that there is no program for medical rehabilitation research within NIH and therefore it is very difficult to find the funding levels. There is no particular agency that is responsible for developing programs, nor are there defined programs established. To the

extent there is funding accounted for which might meet the definition in Title V, it is fortuitous.

With so little significant support for rehabilitation research in any of the NIH agencies, it is apparent that the National Center for Medical Rehabilitation Research could support very substantial amounts of research which is not currently covered by the NIH Institutes. Any research regarding medical rehabilitation and arthritis or amputations could be carried out by the National Center for Rehabilitation Research and would not overlap with existing activity of an Institute. A number of cross cutting fundamental issues in medical rehabilitation such as weakness of the neuromuscular systems, spasticity, loss of sensation and loss of limb would be areas of research that the national center should undertake and that are not undertaken as programmatic initiatives by other Institutes.

5. Why is a National Center for Medical Rehabilitation Research needed now? What is the state of the art of research in this field? How will the Center affect that state of the art and where could we see advances if a Center were created?

The state of the art in research regarding medical rehabilitation as defined in Title V has advanced to the point where major research developments could take place if there was an appropriate focus by an appropriate federal agency. Methods and instruments for measuring functional outcome in patients have been developed to the point where research may be done and produce accurate results regarding the effectiveness of alternative methods of treating various disabilities involving the neurologic system, the musculoskeletal system or the cardiopulmonary system. The capacity to produce new technology for enhancing the physical function of severely disabled patients has improved substantially in the last few years and needs to be built on. The areas of research advances which could be anticipated are in major areas of national need. First, the report of the National Research Council of the National Academy of Science, "Injury in America", indicates areas where advances are to be expected in medical rehabilitation if there was a major research program in medical rehabilitation. These areas include, among others, prevention of contractures, muscular atrophy and joint fixation. The development of research regarding available systems to prevent pressure sores and new techniques to stabilize the head and neck after injury to permit early activities in rehabilitation. Another area where advances could be expected is in the medical rehabilitation related to patients with transplantation of limbs and organs. Another area of likely advances is in the effectiveness of functional electrical stimulation to improve function where neurologic deficits are present. I am attaching to this letter a copy of material submitted for the record at

the hearing which deals with some of these issues.

6. Does the definition of medical rehabilitation research in Title V of S.2222 include developmental disabilities such as Cerebral Palsy or is it limited to injury and trauma?

The definition in S.2222 Title V of medical rehabilitation research involves "the conduct and support of biomedical and related research and other programs with respect to the rehabilitation of individuals with physical disabilities resulting in diseases and disorders of the neurological, musculoskeletal, cardiovascular or other physiologic systems". Clearly, there is not intention to limit the focus of this research on rehabilitation of individuals with physical disabilities resulting from injury or trauma. Clearly, cerebral palsy is one of the major neurologic disabilities with which medical rehabilitation research should be concerned. It was so mentioned in our testimony.

Sincerely,

Bruce Gans

Bruce M. Gans, M.D.

Senator HARKIN. Dr. Gans, thank you very much for your testimony.

Basically, what you are saying is you want the center to bring together all the different rehabilitation research that is being done now in about four different Institutes; you want it brought together under one, right?

Dr. GANS. No, it doesn't necessarily have to focus all the research into the same entity, but there needs to be a coordinating organizational effort.

There is a tremendous need for a well-thought-out and reasoned research plan and agenda to be developed. It may well turn out that it would be more appropriate for specific activities to occur in an existing Institute or center, or other agency within the Federal Government, but what is essential is that a carefully-thought-out plan for dealing with these research issues should happen.

Senator HARKIN. Thank you very much, Doctor.

I am pleased to introduce our next panel of witnesses, who will testify on the need for a National Institute on Deafness and Other Communication Disorders.

We have with us Dr. Bruce Gantz, a Professor of Otolaryngology. He is the Director and Principal Investigator for the Iowa Cochlear Implant Project, a research program supported by NIH to determine how cochlear implants help the deaf hear.

Also with us today is Ms. Marlee Matlin, an actress and winner of an Academy Award for her performance in the film, "Children of a Lesser God." Ms. Matlin is, in her own words, and I quote, "an example of what a deaf person can achieve."

I would also add that she is representative of what Dr. Jordan, the new President of Gallaudet, said here a week ago. He said that it is true that the only thing a deaf person can't do is hear; and I think that Ms. Matlin proves that quite well.

You are just not only an outstanding actress, but we are all just very proud of you.

I look forward to both of your testimonies. I want you to know that I have introduced legislation which would establish a National Institute on Deafness and Other Communication Disorders. I am joined by Senators Simon, Shelby, Cochran, Hecht, Pryor, Inouye, and several others.

I introduced this legislation because I believe that a separate institute, committed to research on hearing, is necessary to bring together a wide range of professionals and focus their work, to give visibility to the needs of the deaf and the speech-impaired population. Dr. Gantz will speak more on this and some of the advances that have been made and what some of the needs are that he sees for the future. Ms. Matlin will follow with her own personal story and talk a bit about the practical significance of research in this area.

We welcome you both here. Ms. Matlin, we certainly welcome you here and look forward to your testimony. I would just say please proceed as you so desire.

**STATEMENT OF MARLEE MATLIN, ACTRESS, TOLUCA LAKE, CA; AND DR. BRUCE J. GANTZ, PROFESSOR OF OTOLARYNGOLOGY, UNIVERSITY OF IOWA HOSPITALS AND CLINICS, IOWA CITY, IA**

Ms. MATLIN [Through voice interpreter]. Thank you.

I want to thank you for allowing me to come here today and talk to you about my concern for the 28 million deaf and hearing-impaired individuals in America. They need your help to be recognized. They need your help and understanding to realize why progress has been so slow.

They do not use white canes, or wheelchairs, so they are quite invisible. Little emotion is evoked, because no one dies of deafness. But I can assure you that deafness, speech and hearing impairments cause enormous emotional pain, frustration, and loneliness.

And every waking moment is spent working to function in a world where people are unaware of the hearing-impaired individual. No one hears his or her needs, his or her desires, or his or her voice.

I applaud Senator Claude Pepper and you, Tom Harkin, for introducing a bill to establish a National Institute on Deafness and Communication Disorders. It is here where dedicated and exceptional doctors could focus their skills on the research we desperately need in order to find answers to the following questions:

Which gene carries deafness?

What causes a sudden hearing loss?

How does sound get from the ear to the brain?

What drugs can cure head and neck cancers that will not cause deafness?

Can cochlear implants be used safely in the profoundly deaf child?

What ways can we reduce hearing loss in the aged?

Why can't hearing aids be individualized like eyeglasses?

How can we prevent one in every 1,000 children from being born deaf or hearing-impaired?

Research for hearing and speech is now conducted in the Neurology Institute. What is desperately needed is a place where these questions can be answered. Please give us national recognition by establishing a separate Institute. It is of immense importance to the over 28 million Americans who are hearing- and communicatively-impaired.

People always want to know how I lost my hearing. At 18 months old, I contracted roseola, baby measles. At that time, public education was poor about early detection of hearing losses, and my family and doctors discovered my loss by mere accident.

Through rehabilitation began immediately, many others like me were not so fortunate, and most likely remained undiagnosed for long periods of time.

The information and help was not available, and it still happens today.

Before I reached the age of five, I learned to lip read or, as they call it now, speech read, and was in an oral program. It was discovered that I had 20 percent hearing in one ear and was profoundly deaf in the other. Shortly thereafter, I learned to sign.

My family also learned sign language. Unlike most families, they sought out information which was not available to them about signing and were very supportive. They made the combination of the two, signing and lip reading, available to me, so that I could communicate with both the hearing and deaf.

I was fortunate that the city in which I lived, Chicago, had the most advanced program for integrating deaf children into their school system. When I entered school at seven years of age, there were classes for deaf students within the regular school. I had an interpreter, wore hearing aids, and could hear simple conversations.

But as a child, I remember always feeling angry because I couldn't hear the phone or music, but especially because other children made fun of me. I was determined never to let this stand in my way and found friends who accepted me for who I was.

At the age of seven, I also entered the Center for Deafness in Des Plaines, Illinois, under the direction of Dr. Pat Scher. This was an after-school program which provided recreation, social activities, interpreters, information and referral services. It was open to deaf people of all ages, and it was here, with other deaf students, that I developed my love for acting.

I then went on to graduate from Hersey High School in Chicago and attended Community College, where I studied criminal justice.

Today, although I have very good speech, I prefer to use interpreters and also rely from time to time on TTYs, a communication device that is similar to a small computer, where messages to other persons can be typed on the TTY keyboard and relayed over the telephone wires onto the screen of another TTY.

The biggest reason why I am supporting the National Institute on Deafness and Communication Disorders is that there are too many people who are deaf or with hearing disorders who have been ignored for so long. Nowhere was this more evident than the events that transpired at Gallaudet University in the last two weeks. It demonstrated the need for this very legislation—to assist through research a large segment of our population who want to participate in and contribute to life as fully as they can. They just need the chance to be recognized.

There are parents who need your support; grandparents, brothers, and sisters. But most of all, it is the children, the children who are struggling to hear, speak, and learn, who seriously need your attention—people who have to cope in the hearing world.

Let me just take a moment from my prepared testimony to say that I am not ashamed to say that I am deaf. I do not see it as an affliction, as a disease. It is a human condition. And to maintain research facilities under the scope of other research facilities denies the fact that deafness and communicative disorders covers more than just not being able to hear; it is something that involves a total individual, and as such deserves the full attention of a separate Institute.

I am an example of what a deaf person can achieve. A separate Institute that focuses on research, prevention, and treatment of hearing, speech, and language disorders can eventually let others achieve their potential as I have. Don't stop them now. They have

too far to go. Just take the time to listen to them. This would mean a great deal to so many people.

Thank you.

[The prepared statement of Ms. Matlin follows:]

STATEMENT OF TESTIMONY

SUBMITTED TO THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

REGARDING THE

NATIONAL INSTITUTE ON DEAFNESS
AND OTHER COMMUNICATION DISORDERS

BY

MARLEE MATLIN

MARCH 29, 1988

Mr. Chairman, Members of the Subcommittee, and guests, my name is Marlee Matlin and I am an actress.

I want to thank you for allowing me to come here today to tell you of my concerns for the 28 million deaf and hearing impaired Americans.

They need help to be recognized. They need your help and understanding to realize why progress has been so slow. They do not use white canes or wheelchairs, so they are quite invisible. Little sympathy is evoked because no one dies of deafness. But I can assure you, deafness, speech and hearing problems cause enormous emotional pain, frustration and lonliness. And every waking moment is spent working to function in a world where people are unaware of the hearing impaired individual: his or her needs, desires, and voice.

I applaud Senator Claude Pepper and you, Senator Tom Harkin, for introducing a bill to establish a National Institute on Deafness and Communication Disorders. It is here where dedicated and exceptional doctors could focus their skills on the research we desperately need in order to find answers to the following questions:

- Which gene carries deafness?
- What causes sudden hearing loss?
- How does sound get from the ear to the brain?

- What drugs can cure head and neck cancers that <u>will not</u> cause deafness?
- Can cochlear implants be used safely in the profoundly deaf child?
- What ways can we reduce hearing loss in the aged?
- Why can't hearing aids be individualized like eye glasses?
- How can we prevent one in every thousand children from being born deaf or hearing impaired?

Research for hearing and speech is now conducted in the Neurology Institute. We want a home of our own, where we can decide how these questions can be answered. Please give us national recognition by establishing a separate Institute. It is of immense importance to millions of Americans who are communicativly impaired.

People always want to know how I lost my hearing. At eighteen months old, I contracted roseola (baby measles) and my hearing loss was diagnosed only after a few days. Although at that time, public education was poor about early detection of hearing losses, my family and doctor discovered my loss fairly quickly, compared to many similar cases, thereby beginning my intensive rehabilitation.

Before I reached the age of five, I learned to lip read, or, as they call it now, speech read, and was in an oral program. It was discovered that I had 20 percent hearing in one ear and was profoundly deaf in the other. Shortly thereafter, I learned to sign.

My family also learned sign language, which I now understand was very unusual. Unlike most families, they had information available to them about signing and were very supportive. They made the combination of the two, signing and lip reading, available to me, so that I could communicate with both the hearing and the deaf.

I was fortunate that the city in which I lived, Chicago, had the most advanced program for integrating deaf children into their school system. When I entered school at seven years of age, there were classes for deaf students within the regular school. I had an interpreter, wore hearing aids and could hear simple conversations.

As a child, I remember always feeling angry because I couldn't hear the phone or music, but especially because other children made fun of me. I was determined never to let this stand in my way and found friends who accepted me as I was.

At the age of seven, I also entered the Center for Deafness in Des Plaines, Ill under the direction of Dr. Pat Scher. This was an after school program, which provided recreation, social activities,

interpreters, information, and referral services. It was open to deaf people of all ages and it was here, with other deaf students, that I developed my love for acting.

I went on to graduate from Hersey High School in Chicago and attended Community College.

Today, although I have very good speech, I prefer to use interpreters and also rely on TTY's, a communication device similar to a small computer, where messages to another person can be typed on the TTY keyboard and relayed over telephone wires onto the screen of another TTY.

The biggest reason I am supporting The National Institute on Deafness and Communication Disorders is that there are too many people who are deaf or with hearing disorders who have been ignored for so long. Nowhere was this more evident than the events that transpired at Gallaudet University in the last two weeks. It demonstrated the need for this very legislation: to help, through research, a large segment of our population, who want to participate in, and contribute to life as fully as they can. They just need the chance.

There are parents who need your help, grandparents, brothers, and sisters; but most of all, it is the children . . . the children who are struggling to hear and speak and learn, who seriously need your help.

I am an example of what a deaf person can achieve. A separate Institute that concentrates on research to find preventions, treatments, and cures of hearing, speech and language disorders could eventually allow others to achieve their potential as I have. Don't stop them now. They have too far to go. Just take the time to listen to them.

Thank you for the opportunity to appear before you today to urge you, with all my heart, to establish a separate Deafness and Communication Disorders Institute. It would mean so much to so many.

Senator HARKIN. Ms. Matlin, thank you very much for wonderful testimony.

Listening to you tell about your early years sounds very familiar to me. My brother is a lot older than you—he is a lot older than I, as a matter of fact—but I remember when he was in school. At that time, there were three things that a deaf person could be when they went to the Iowa School for the Deaf—I think, if I am not mistaken—they could be a printer or a shoe cobbler or a baker. And they asked him which he wanted to be, and he said, "None of the above." But that was not an acceptable answer.

So they told him he was going to be a baker which, of course, he never, ever wanted to be—although he is not a bad baker.

But you can imagine the frustration of an individual wanting to express himself or herself and being told that you are limited, that you cannot do these things.

So I have seen that frustration, and I just know how awful it can be. And I am also very sensitive, and it is something that a lot of people don't understand about deaf people. You are right—when a blind person is out there with a cane, you know that that person is blind. But a deaf person, you don't know. And the barriers that are erected are just immense.

I don't know why I never thought of this before, Marlee—if I can use your first name—but I asked someone one time why it is that people have thought that deaf people couldn't learn, and even why today there is still that resistance to understanding that deaf people can do anything. And this person responded to me and said, "Well, you know, for years and years, deaf people went to schools that were called 'the school for the deaf and dumb.' "

I never thought about it, but my brother went to the Iowa School for the Deaf and the Dumb—but he was never dumb. And I think somehow that embedded itself in people's minds for years and years.

I look back now on the times I used to travel with my brother or watch him in situations, and as soon as the hearing person found out that he couldn't speak, it was as thought they could not even deal with it, and I guess maybe that was because, well, he was "deaf and dumb."

Well, we have come a long way since then, and I think what has happened at Gallaudet the last few weeks has just been a marvelous thing, as I said here a week ago. And I am hopeful that we can really take some large steps with this Institute, with what has happened at Gallaudet, to really understand that we have ignored—and I mean really ignored—the problems of our deaf population for a long time.

Just to tell you another little story, I remember when my brother first got his decoder and how great that was. I had a lot of hope for decoders. But most deaf people don't have very much money. They are very low-income, they don't have much money. The decoders cost a lot of money. I tried to get through a bill to give a tax credit to everyone who would buy a decoder, and I couldn't even get that through. But maybe with what happened at Gallaudet, maybe we can get that done.

So I think the world of the deaf has been changed irrevocably for the good with what happened at Gallaudet recently, and I am glad I was able to see it in my own time.

Well, thank you very much. Your story just makes me think of so many things.

Ms. MATLIN. Thank you.

Senator HARKIN. I know what you went through, and what you have achieved is just, again, something that gives hope to so many people in this country. So keep up your fine work.

What is your next movie? [Laughter.]

Well, thank you.

Do you have anything else that you would like to add? I want to respect your time commitment.

Ms. MATLIN. Well, I can just say briefly that I am aware, or I trust your feelings in relation to the deaf individuals in the United States. I went through a great deal of hard times. But now, as I have had a chance to grow up slowly, I have become overcome by the fear of being a deaf person, and I won't let anyone manipulate me or control me. But there is still a great deal of anger in me that I have and that I see so many deaf people who have been hurt—as well as hearing people, especially parents of deaf children.

But I trust you, and I trust what will happen in the future and that it will be accomplished, what we are trying for.

Senator HARKIN. Well, I can assure you we are going to do what we can, and we look forward to working with you as we move ahead. I hope we'll get this National Institute.

Ms. MATLIN. Same here.

Senator HARKIN. Thank you. If you would like to go, you may. I would prefer to have you stay, but——

Ms. MATLIN. I will see you later. I do have an appointment.

Senator HARKIN. Okay. Thank you very much again.

All right. Dr. Bruce Gantz—Dr. Gantz, as I said, is from the University of Iowa. He is leading a research program there dealing with cochlear ear implants

I have had occasion to deal with Dr. Gantz several times over the last couple of years, and Dr. Gantz, I have a copy of your statement. It will be made a part of the record in its entirety, and again I would ask you to please proceed as you so desire.

Dr. GANTZ. Thank you very much, Senator Harkin.

I am pleased for the opportunity to testify before the Subcommittee on Labor and Human Resources in support of the creation of a new Institute for Deafness and Other Communicative Disorders.

As you have said, I am a professor of otolaryngology at the University of Iowa. I teach and take care of patients with ear, nose and throat problems. I am also the director of the cochlear implant research program at the University of Iowa that is supported by the National Institutes of Health to determine how cochlear implants help the deaf to hear.

Throughout the United States, there are only 220 other researchers supported by the NIH to investigate the causes, diagnoses, and treatment and prevention of the disorders that affect how we communicate with each other. These investigators are exploring a broad range of problems—from understanding why a young child

does not learn language to why the elderly cannot understand what a person is saying to them.

For many years, researchers studying the communicative disorders and diseases have received support from the National Institutes of Health through the institute known as the NINCDS—the National Institute of Neurological and Communicative Disorders and Stroke. But this current structure is no longer adequate to provide the necessary direction and focus for the research required to address the problems of 28 million Americans who suffer from a hearing, balance, speech or language disorder. That is one-tenth of our population in the United States, and that figure does not include an additional 34 million people who are troubled with ringing in their ears and visit the doctor frequently because of it.

This astounding figure of 28 million has been published in an NINCDS booklet developed from data for 1987. These data also identify 48 million people in the United States as having a major neurological disorder or communicative disease.

Therefore, almost 60 percent of the people with disorders that the Neurology Institute, or the NINCDS must address, are really disorders of deafness and communication. Yet, less than 14 percent of the present NINCDS budget is directed toward research focusing on hearing and communication.

Why does this disparity of research effort exist?

First, since its development in 1950, the Neurology Institute has been organized, directed and dominated by neurologists and neurosurgeons whose training and interests are directed at diseases and research that primarily address the problems of the brain and spinal cord.

Otolaryngologists, audiologists, and speech pathologists, on the other hand, have the responsibility for diagnosing and managing diseases that for the most part affect the end organs of hearing, balance and voice.

A single institute cannot be expected to give adequate attention to either set of responsibilities when the clinical and scientific approaches to their diseases are so diverse. This fact was well-illustrated several weeks ago when the NINCDS Director presented his annual appropriations testimony before the House of Representatives, and it only included one paragraph on deafness. Fifteen other paragraphs were devoted to the neurological disorders and none addressed any of the other communicative disorders.

Second, it has only been in the past ten years that significant breakthroughs in electronics and miniaturization have allowed us to study the balance and hearing organ. But these advances have quickly altered our management of such problems as total deafness in adults.

Today, the cochlear implant is the recommended treatment for patients who have lost their hearing after learning language. This is the first time we have been able to offer any treatment for inner ear deafness, or what in the past has commonly been called "nerve deafness". We are now exploring the use of this technology in deaf children and hopefully, we will be able to advance the language skills beyond the fourth grade reading level that you talk about that the average deaf person attains.

The cochlear implant is now the model for the clinical application of all types of neuro-prostheses. But breakthroughs are beginning to occur in other places of our field. New vaccines to control ear disease, ear infections, the most common reason a child visits a physician, are on the verge of development, and we now have the technology to develop hearing aids that will enhance word understanding in a noisy environment in addition to amplifying sound.

But we have no sponsored research to support any of these efforts. Another contributing factor to the disparity of research effort is that in the past there has been a lack of researchers interested in the communicative disorders. This is rapidly changing today. The cadre of researchers interested in deafness and communicative diseases is expanding. There are over 900 members of the Association for Research in Otolaryngology, and the interest in our specialty has never been greater. This year, there were over 700 medical students applying for 248 first-year residence positions in otolaryngology.

This renewed interest in otolaryngology and related research stems from the exciting new advances taking place in all areas of our field.

Twenty years ago, Congress had the wisdom to separate eye research from the Neurology Institute, because of an overwhelming need to study vision and blindness. At that time, the Neurology Institute voiced the same objections to that separation as are being expressed today by the NINCDS.

Senator HARKIN. Bruce, I am going to have to ask you to summarize. I have a meeting at five o'clock that I can be a little bit late for, but I have got to be there.

Dr. GANTZ. Fine. I just wanted to say that the NEI has been able to support over 1,400 grants for 12 million people, while we only have 200 grants for over 18 million hearing-impaired people.

I could go on and describe all of the debilitating disorders that make it impossible for people to communicate with their fellow man and incur medical costs of over $30 billion annually. But I think you've got the picture. The health of these 28 million Americans is not being adequately addressed as long as the biomedical research to solve their problems is hidden under the umbrella of the Neurology Institute.

A separate Institute for communicative disorders must be created to allow effort by a growing, strong and talented group of researchers and clinicians, dedicated to solve the problems of the communicatively handicapped, by learning what causes them, how to better diagnose them, treat them, and hopefully prevent them in the future.

Thank you for allowing me to share these thoughts with you.

[The prepared statement of Dr. Gantz follows:]

Statement

by

BRUCE J. GANTZ, M.D.

Professor
Department of Otolaryngology--Head and Neck Surgery

UNIVERSITY OF IOWA HOSPITALS AND CLINICS

Iowa City, Iowa 52242

Before
Committee on Labor and Human Resources

U.S. Senate

On S. 1727 to establish a National Institute on
Deafness and Other Communication Disorders

March 29, 1988

Senator Harkin, members of the Committee on Labor and Human Resources, I am pleased for the opportunity to testify in support of the creation of a new Institute for Deafness and Other Communicative Disorders. I am Dr. Bruce Gantz, a professor of otolaryngology at the University of Iowa. I teach and take care of patients with ear, nose and throat problems. I am the director of the cochlear implant research program at the University of Iowa that is supported by the National Institutes of Health to determine how cochlear implants help the deaf to "hear." Throughout the United States, there are only 220 other researchers supported by the NIH who are dedicated to seeking the answers to questions surrounding the causes, diagnosis, treatment and prevention of all disorders and diseases that affect how we communicate with each other. These investigators are exploring a broad range of problems--from understanding why a young child does not learn language and start to speak at a normal age to why the elderly cannot understand what a person is saying to them.

For many years, researchers investigating communicative disorders and diseases have received support from the National Institutes of Health through the institute known as the NINCDS--National Institute of Neurological and Communicative Disorders and Stroke. But, the current structure is no longer adequate to provide the necessary direction and focus for the research required to address the problems of the 28 million Americans who suffer from a hearing, balance, speech or language disorder. That is 1/10 of our population, and that figure does not include an additional 34 million people that are troubled with ringing in their ears & visit the doctor frequently because of it.

This astounding figure (28 million) has been published in an NINCDS booklet developed from data for 1987. These data also identify the prevalence of the major neurological and communicative disorders in the United States at almost 48 million people. Therefore, almost 60% of the people with disorders that the "Neurology Institute" must address are really disorders of deafness and other communication problems. Yet less than 14% of the present NINCDS budget is directed toward research focusing on hearing and communication.

Let us examine some of the reasons why this disparity of research effort exists.

First, since its development in 1950, the "Neurology" Institute has been organized, directed, and dominated by neurologists and neurosurgeons whose training and interests are directed at diseases and research that primarily address problems of the brain and spinal cord. Otolaryngologists, audiologists, and speech clinicians, on the other hand, have the responsibility for diagnosing and managing diseases that for the most part affect the end organs of hearing, balance and voice. A single Institute cannot be expected to give adequate attention to either set of responsibilities when the clinical and scientific approaches to their diseases are so diverse. This fact was well illustrated several weeks ago when the NINCDS director presented his annual appropriations testimony before the U.S. House of Representatives and included only one paragraph on deafness. Fifteen other paragraphs were devoted to neurological disorders and none addressed any of the other communicative disorders.

Second, it has been only in the past 10-20 years that significant scientific breakthroughs in electronics and miniaturization have allowed us to study the hearing and balance organ. But, these advances have quickly altered our management of such problems as total deafness in adults. Today the cochlear implant is the recommended treatment for patients who have lost their hearing after learning language. Just five to seven years ago the ethics of placing these devices in human beings was being debated. Breakthroughs are beginning to take place in other areas of our field. New vaccines to control ear infections in children, the most common reason children visit a doctor, are on the verge of development. And we have the technology to develop hearing aids that will enhance word understanding in addition to amplifying sound.

Another factor contributing to this disparity of research effort has been the lack of researchers interested in communicative disorders. This is rapidly changing. Today, the cadre of researchers interested in deafness and communicative diseases is expanding. There are over 900 members of the ARO--Association for Research in Otolaryngology and the interest in our specialty (otolaryngology) has never been greater. This year there were over 700 medical students applying for 248 first year residency positions. A greater number of these students are in the top 15% of their class. This renewed interest in otolaryngology and related research stems from the exciting new advances taking place in all areas of our field.

Twenty years ago Congress had the wisdom to separate eye research for the "Neurology Institute" because of an overwhelming need to study vision and blindness. At the time, the "Neurology Institute" voiced the same objections to that separation as are being expressed by the NINCDS today. Without question it is well recognized today that the NEI has become an important and meaningful factor in vision research. It is gratifying to see the advances that they have been able to accomplish since its separation. Today the NEI is able to support over 1400 grants on vision related research affecting over 12 million Americans. It is incredible to think that only 200 research grants are available to solve the hearing problems of 20 million people. If all of the communicative disorders are counted (afflicting 28 million Americans), we are still only able to support 400 grants. Colleagues of mine in ophthalmology have shared a booklet with me from the Eye Institute which shows that 17 clinical trials, each involving multiple centers, are now in progress on such important topics as laser therapy for diabetic eye disease and glaucoma. We can only point to three similar types of studies in our discipline: the one I direct on cochlear implants and two dealing with ear infections. All three involve single centers. The goal of clinical research is to provide information that will help the practitioner treat patients more effectively. Clinical trials provide the best means to compare new or alternative methods of treatment, and thus lead to the most effective and cost-efficient way to manage a disease. There is no reason to believe that we cannot make as great strides in the treatment of ear diseases and communicative disorders as the eye researchers have made in solving vision problems. We simply need the opportunity to do so. We cannot come close to fulfilling our mission when we receive less than 15% of the "Neurology Institute" appropriation.

As you are aware, considerable research is carried out on the NIH campus itself. The NINCDS has 12 laboratories and 9 branches to conduct both basic and applied clinical research. Only one of these 21 intramural research sections is dedicated to research in the area of communicative disorders. My question is: why this inequity of research support for the myriad of disorders that afflict 28 million communicatively impaired?

If you think I am overstating the size of the hearing-impaired population now, you will be amazed at the number of affected Americans we will be dealing with as our population continues to age. One of the most insidious conditions which we all will face eventually is presbycusis--the inability to hear and understand what is spoken as we age beyond 60. More than 11% of our population was over 65 in 1983. It is estimated that by 2025 that figure will rise to 17.2%. A conservative estimate of the folks that have a hearing loss severe enough to keep them from understanding the TV or what their companion or grandchild is saying to them is 16%. These figures translate into the following: over 4 million senior citizens have significant hearing impairments now, and by 2025 that number will grow to more than 10 million people.

Let me turn now to a profile of the youngsters whom I see in my practice with a severe to total inability to hear and consequently rarely develop language and speech as you and I know them. This occurs in about 1 in 1000 births while thousands more are rendered deaf due to infections and drugs used in the treatment of life-threatening illness. It is important for you to understand that the average deaf child only attains a fourth grade reading level because of the lack of sound input which is so necessary for language development. In 1988 we do not know which patients have genetically transmitted deafness. If we could determine which disorders are congenital verses those which are inherited, we could benefit from greatly improved methods for preventing each and possibly in treating the disorders.

I could go on and on describing all of the debilitating disorders that make it difficult or impossible for people to communicate with their fellow man and cost the American public over 30 billion dollars annually. But I think you have the picture. The health of these 28 million Americans is not being adequately addressed as long as the biomedical research to solve their problems is hidden under the umbrella of the "Neurology Institute." A separate Institute for communicative disorders must be created to allow 100% effort by a growing, strong and talented group of researchers and clinicians in order to solve the problems of the communicatively handicapped by learning what causes them, how to better diagnose and treat them and hopefully to prevent many of them.

Thank you very much for allowing me to share these thoughts with you.

Senator HARKIN. Thank you. I really didn't want to cut you off; I just wanted you to give a good summary, if you could, and I do have your statement.

The National Eye Institute, you say, supports over 1,400 grants, affecting 12 million Americans; but only 200 research grants are available to solve the hearing problems of 20 million people.

Dr. GANTZ. That's right.

Senator HARKIN. I think that says it all right there.

Again, as I just said to Ms. Matlin, it is the same thing. The hearing-impaired just have not gotten the same kind of visibility and interest and support that others have had in the past, even though it is a much broader-based disability.

Basically, what I want to ask you, Bruce, is this. I have some questions I really need your answer on. A couple people have pointed out to me that grant applications in the area of deafness research are awarded at a 50 percent rate. As they say, how much more can we do for you? What would be your response to that?

Dr. GANTZ. That is interesting, because that was the same argument that the Neurology Institute had in 1968 when the eye people, the ophthalmologists, approached them for a separation of a new Institute.

I think the one thing it shows is the quality and maturity of our science, the fact that we are getting 50 percent funding rate. But it also illustrates the frustration that many of the researchers in the United States have in the communicative disorders, because we don't have enough grants to be funded, and so the number of people applying has been reducing, because when you apply for a research grant, it takes a considerable effort and amount of time. Some of these grants are 600 or 700 pages and take six to eight months to develop. And when they get approved and not funded, how many times are you going to continue to do that?

We have had 15 percent of the grants in the Neurology Institute for the last 10 to 15 years. This percentage does not increase. So that is one of the reasons why you don't have as many people applying.

But I think that the quality is out there, and the support that the Eye Institute got and the effort that they have today illustrates that this is not a very good argument.

Senator HARKIN. You mentioned in your testimony that we now have the technology to develop hearing aids to enhance word understanding in addition to amplifying sound.

I am going to be holding some hearings in the spring on assistive technologies for the disabled, of all and various means, so I am very interested in this. Can you tell me what is being done currently?

Dr. GANTZ. Well, I think there are a number of things going on. First of all, we have found that the cochlear implant has been extremely successful in the totally deaf population, and we are looking at ways to expand the indications for these kinds of devices. For example, we only implant people who are totally deaf now and cannot even hear themselves talk. Hopefully in the next few years, we will be able to implant people who understand 5 to 10 percent or 20 percent of what is said, and get them up to 100 percent.

But in the area of digital hearing aids, there are ways of filtering out noise and amplifying speech, and these efforts need to be supported and expanded.

There are also new efforts to develop totally implantable hearing aids that will bypass the conductive mechanisms, mostly the conductive mechanisms, and allow us to stimulate the inner ear directly, and hopefully these will help get rid of some of the distortions that are present when you have to amplify sound tremendously in the ear canals, where all kinds of standing waves and distortions occur; I think you know if you have been around somebody when they turn up their hearing aid, it starts to whistle. That is distortion within the ear canal. We can bypass that, hopefully, and be able to totally implant these devices and enhance word understanding.

Senator HARKIN. How much research is being done on tinnitus?

Dr. GANTZ. I can show you some figures. I think we have $223,000, that is 10 percent of three research grants. You know, that is one of our major problems, ringing in the ears. We have patients coming to us all the time with complaints of ringing; and asking what we can do for it, We can't do anything for it, because we don't understand if it is in the ear or in the brain.

So our efforts in that area need to be expanded tremendously.

Senator HARKIN. One last thing. What do you see as the possible area of perhaps greatest breakthrough with some kind of focused research? What area would you say might hold the greatest opportunity?

Dr. GANTZ. I think that again is very difficult to pinpoint one area, because we have so many areas that are just on the verge of breaking through, with the potential vaccines for otitis media, or ear infections for children; the ability to develop better hearing aids for the estimated 10 million adults who will be hearing-impaired due to aging by the year 2025. These are some of the things that we need to do.

We need to study balance. There are 40 percent of the people in this country who at least at one time complain of some balance disturbance, and a number of these become chronic. And we have very little to offer this, except cutting the nerves of the balance organ, and they are then debilitated with other kinds of problems after that.

So there are myriads of problems that need to be addressed and can be addressed if we had the support. And I think we can have that strong effort if we develop a single Institute to focus on these problems and take them away from an Institute that has its emphasis in other directions.

Senator HARKIN. Thank you very much. Is there anything else you would like to add, Bruce?

Dr. GANTZ. No. I just want to thank you for your support and effort here, and I hope we can do this together.

Senator HARKIN. I do, too. I have expectations that we will be able to get this done this year. I appreciate what you said about the single paragraph that is included in the testimony on the House side. We will see if there is a little bit more in the Senate side when they come up here.

Dr. GANTZ. Thank you.

[Additional material supplied for the record follows:]

# THE AMERICAN ACADEMY OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY, INC.

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March 29, 1988

Testimony of the American Academy of Otolaryngology-Head and Neck Surgery in support of S. 1727

The American Academy of Otolaryngology-Head and Neck Surgery represents the 8,000 physicians and surgeons who provide specialty health care for the 25 percent of the population who are affected by disorders of the ears, nose, throat, and head and neck regions. The Academy, being strongly in favor of the passage of S. 1727, the bill to establish a National Institute of Deafness and Other Communication Disorders, appreciates the opportunity to enter written testimony into the record of this hearing before the Senate Labor and Human Resources Committee.

The Academy shares the widespread reluctance to interfere with the vital missions of the National Institutes of Health and opposes any unrestrained proliferation of new institutes. Indeed, we have long acted in support of the Communicative Disorders Program within the National Institute of Neurological and Communication Disorders and Stroke, commonly known as the 'Neurology' Institute.

Until recently, the NINCDS has been a good home for this research effort, but the growth of scientific knowledge and opportunities has now reached the point where real progress in preventing and treating Communicative Disorders is within reach. This progress cannot be fully realized if Communicative Disorders remains an "add-on" to the Neurology Institute. Current research on deafness and other communication and neurosensory disorders and their rehabilitation is fragmented among 5 of the Institutes as well as several Bureaus and Agencies. There is an urgent need to consolidate these multiple programs and to establish identifiable core groups of administrative and advisory personnel to direct biomedical research in this critical field on an ongoing daily basis. At the present time there is no effective coordination of either planning or implementation of research programs. There are no core individuals who are collectively accountable to Congress and to the millions of communicatively impaired and disabled citizens who look to NIH-supported research for hope and tangible help.

The Academy and its members have long provided support to the NINCDS through the service of its scientist members on study sections and Advisory Councils, through participation in review panels and conferences, through testimony before the Congress, and, for the past five years, by an intense campaign to attract more physicians to careers in contemporary clinical research. To this latter end, the Academy sponsored two national conferences on Research Goals and Methods in Otolaryngology. As a result, the numbers of basic and clinical investigators in communicative disorders research are steadily increasing each year and would grow even more vigorously if there were signs that NIH and Congress truly are encouraging research and research training in this area. However, in spite of several comprehensive reviews of the research needs and opportunities in the fields of deafness and communicative disorders NINCDS has yet to develop a clearly articulated plan for their implementation. For example, the cochlear implant - the first major advance in providing hearing sensation to the totally deaf - was developed, field-tested, and approved for patient use by practitioner members of the Academy. This device, the first technique for direct sensory input into the central nervous system, came into existence without any primary involvement or leadership from the NINCDS.

The Academy is painfully aware of the pressures being mounted by the hearing-handicapped citizens of this country for similar new advances using modern technology to meet their needs. They have come to expect progress of the magnitude generated by the National Eye Institute, which was created out of the "Neurology" institute in 1968. The NEI currently has 17 clinical trials in progress studying new techniques for eye care; there are only three sponsored by the NINCDS in the field of hearing research. Given the fact that there are twice as many deaf citizens as blind ones, it seems highly inequitable that four times as much money and 7 times the number of grants focus on eye research as upon ear research. Given the increasing number of older citizens with their higher incidence of hearing and balance disorders, citizen pressure will only increase.

A final and the most critical area to be examined is the availability of trained men and women who are able to apply the basic scientific resources to the clinical problems. These are the physician scientists, the clinical researchers. These clinical investigators will predominantly have their medical training in the area of Otorhinolaryngology, a discipline which encompasses both medicine and surgery as does ophthalmology. It is in the area of the availability of the clinical investigators in which there has been the largest problem. The lack of clinical investigators in the area of hearing and vestibular disorders has been recognized. The situation is worse for the other communicative disorders. During the past decades the various directors of the NINCDS have been telling the academic otolaryngic community that there have been very few otolaryngologists applying for grants and that is why there were so few given and consequently why there has been such slow advancement in the area of hearing and vestibular disorders when compared to similar disciplines. Thus far in 1988, three existing otolaryngology research training grants have not been renewed by NINCDS, and a new program proposed was not funded. An already shaky situation is being allowed to deteriorate further.

During 1987 there were approximately 20 grants funded through the NINCDS, both competing and noncompeting renewals, in which a clinical otolaryngologist was the principal investigator. This is contrasted to the National Eye Institute (NEI) in which there were 250 grants in which the Principal Investigator was an Ophthalmologist. Within the NINCDS 595 grants were given in 1987 in which the Principal Investigator was either a Neurologist or a Neurosurgeon. Up to now there has been no meaningful solution to this problem of the lack of otolaryngologist investigators. We submit that lack of research interest among otolaryngologists is no longer the problem. This situation is continuing even though a large segment of the nation is being penalized by not having their health needs met.

A comparison must be made with two similar disease types, Neurological and Ophthalmological disorders. Both of these groups of diseases are areas in which many advances have been made and continue to be made which provide prevention and cure of a large number of different diseases. These advances have been based upon the application of basic science to human problems. This has been a successful strategy which has resulted, in these and other areas, in a significant enhancement of the health and quality of life of the American people. Some examples are the understanding of the genetics of tumors such as the retinoblastomy of the eye and the neurofibromatosis of the nervous system (the elephant man's disease). Both of these are genetic diseases whose understanding has come about through the application of molecular genetics. The list of such applications in the areas of the eye and the nervous system is long and includes such entitles as color blindness, Huntingtons chorea, Refsums disease, the mucopolysaccharidosis, and many others.

However, the comparable list for hearing and vestibular disorders is quite short. Except for those which have been identified because of their neurological or ophthalmological or other associated problems, there have been none. There are many diseases of the hearing and vestibular systems which should be able to be understood by the application of the same general techniques which have been used in the neurological, ophthalmological and almost all other fields of medicine. It is estimated that at least one-half of all permanent and progressive hearing impairments are of genetic origin. This is one of the most obvious areas which can be explored using contemporary, basic molecular science.

It has become apparent that a stand-alone institute specifically devoted to a set of problems possesses the efficiency and focus to effectively implement its goals. Therefore the Academy has, after due consideration of alternatives, come to the conclusion that the time has come to separate the research effort in hearing and the sciences of speech, language, balance, taste and smell - collectively known as the communication disorders - from the "Neurology' institute and to unite them together under one umbrella, a National Institute of Deafness and Other Communication Disorders.

In 1984 the Institute of Medicine promulgated 5 criteria for the establishment of a new institute within the NIH. The Academy finds convincing evidence that the new institute proposed in S. 1727 fulfills these criteria.

Criterion 1: The activity of a new institute ... must be compatible with the research training mission of NIH.

The purpose of a new institute is clearly for research and research training. No regulatory or service function is envisioned or proposed.

Criterion 2: It must be demonstrable that the research area of a new institute ... is not already receiving adequate or appropriate attention.

The Academy believes that the arguments presented above attest fully to the inadequacy of attention being paid to the research needs of the communicatively handicapped.

Criterion 3: There must be reasonable prospects for scientific growth in a research area to justify the investment in a new institute ...

The remarkable growth over the past decade of basic science knowledge about the auditory system, about speech encoding and perception, about audiovestibular neurotransmitters, about cochlear micromechanics plus the fact that there are new more scientists working in this field that ever before makes it abundantly clear that it is the growth in scientific effort - in contradistinction to the lack of growth of its research funding - that is one of driving forces for the new institute.

Criterion 4. There must be reasonable prospects of sufficient funding for a new institute ...

The President's budget for the NINCDS for FY89 is $577.1.M. If a neutral-cost funding o9f the new institute were to be adopted, the 19 percent of that budget traditionally allocated for Communicative Disorders would provide a budget of $109.6 M. Overhead expenses are generally estimated at 6.2 percent of the total budget. This would more than provide the $4 M in start-up funds necessary to initiate a new institute plus $2.5 M in discretionary dollars that would permit the new institute to begin new initiatives.

Criterion 5. A proposed change in the NIH organizational structure should, on balance, improve communication, management, priority setting, and accountability.

The Academy believes that the proposed new institute will accomplish all the objectives of this criterion. Pulling the already fragmented research effort in Communication Disorders under one administration will indeed improve communication and management. Having the sole focus of the new institute rest upon Communication Disorders will facilitate priority setting. For example, if the Director of the NINCDS must choose between allocating scarce funds for research into brain tumors, on the one hand, or for hearing disorders (which are only fatal when the victim cannot hear an alarm), on the other hand, there is a strong proclivity, when choices must be made, to fund the more-serious disorder rather than quality of life research.

The Academy appreciates the opportunity to share its views with the Committee.

TESTIMONY

OF

ASSOCIATION FOR RESEARCH IN OTOLARYNGOLOGY

BEFORE

THE COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
EDWARD M. KENNEDY, CHAIR

ON
S. 1727:
TO ESTABLISH A NATIONAL INSTITUTE
ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

MARCH 29, 1988

Testimony of the Association for Research in Otolaryngology
in support of S. 1727.

The Association for Research in Otolaryngology is composed of over 900 basic scientists and physician-investigators comprising the majority of researchers who study the structure, function, and disorders of the body systems concerned with hearing, balance, speech, voice, taste and smell. The Association for Research in Otolaryngology supports the passage of S.1727, the bill to establish a National Institute of Deafness and Other Communication Disorders and appreciates the opportunity to enter written testimony into the record of the hearing conducted by the Senate Labor and Human Resources Committee, March 29th, 1988.

The members of the Association for Research in Otolaryngology have participated actively in the National Institute of Neurologic and Communicative Disorders and Stroke, commonly known as the 'Neurology' Institute. The NINCDS has provided a good home for our research effort but the growth of our science has exploded beyond the point where Communicative Disorders can rightfully be retained as an 'add-on' to the Neurology Institute. Indeed, our scientists and clinical investigators receive funding from 5 of the Institutes as well as several Bureaus and Agencies. There is an urgent need to consolidate these multiple programs and to establish identifiable core groups of administrative and advisory personnel to direct biomedical research in this critical field on an ongoing daily basis. At the present time there is no effective coordination of either planning or implementation of Communication Disorders research programs within the NIH. There are no more than 10, perhaps as few as 4, core individuals in the NIH who are collectively accountable to Congress and to the millions of communicatively impaired and disabled citizens who look to NIH-supported research for hope and tangible help.

The Association for Research in Otolaryngology is the fastest-growing organization in this field: our numbers increase by 10 percent annually. Our members have worked with and supported the NINCDS through service on study sections and Advisory Councils, through participation in review panels and conferences, and, most importantly, by conducting the bulk of research in Communication Disorders. The Association for Research in Otolaryngology has also worked with other organizations, notably the American Academy of Otolaryngology-Head and Neck Surgery to help attract physicians into research careers. The fact that our scientists have received priority scores and funding rates among the highest in the NINCDS has been noted in reports from the NINCDS and attests to maturity and excellence of our science.

The Association for Research in Otolaryngology is acutely aware of the pressures being mounted by the hearing-handicapped citizens of this country for new advances using modern technology to meet their needs. They have come to expect progress of the magnitude generated by the National Eye Institute, which was created out of the 'Neurology' institute in 1968. The NEI currently has 17 clinical trials in progress studying new techniques for eye care; there are only three sponsored by the NINCDS in the field of hearing research. Given the fact that there are twice as many deaf citizens as blind ones, it seems highly inequitable that four times as much money and 7 times the number of grants focus on eye research as upon ear research. Because of the increasing number of older citizens, who have a greater incidence of hearing and balance disorders, citizen pressure will only increase in the future.

Tremendous advances have been made in the last decade in our understanding of the physiology and mechanics of the inner ear. With added support, it is hoped that these basic advances can continue and be translated into clinical applications that might offer hope for prevention or even cure, in some cases, for the common afflictions of noise-induced and old-age hearing loss. Similar advances are just beginning in our understanding of taste and smell. There are many diseases of the hearing and vestibular systems which should be able to be understood by the application of basic science to human problems. This has been a successful strategy which has resulted, in other biomedical areas, in a significant enhancement of the health and quality of life of the American people. It is estimated that at least one-half of all permanent and progressive hearing impairments are of genetic origin. This is one of the most obvious areas which can be explored using contemporary, basic molecular science.

However, in spite of several comprehensive reviews of the research needs and opportunities in this field there yet remains to be developed by the NINCDS a clearly articulated plan for their implementation. For example, the cochlear implant - the first major step forward in providing a semblance of hearing for the totally deaf - was developed, field-tested, and approved for patient use by private practitioners of Otolaryngology. The cochlear implant is the first technique for direct sensory input into the central nervous system and it came into existence without primary involvement or leadership from the NINCDS. Thus, one wonders how much more advanced this technique would have been if the NIH had been involved from the beginning in its testing and development. The greatest technical advances in this area have been made recently in Australia where government support has been generous.

The Association for Research in Otolaryngology shares the widespread reluctance to interfere with the vital missions of the National Institutes of Health and has opposed unrestrained proliferation of new institutes. However, it has become apparent that only a stand-alone institute specifically devoted to communication disorders has the efficiency and focus to effectively develop and implement a strategic plan to meet the research needs of communicatively-impaired citizens. Therefore, the Association for Research in Otolaryngology has, after due consideration to alternatives, come to the conclusion that the time has come to split off the research effort in hearing and the sciences of speech, language, balance, taste and smell - collectively known as the communication disorders - away from the 'Neurology' institute and to unite them together under one umbrella, a National Institute of Deafness and Other Communication Disorders.

In 1984 the Institute of Medicine reported 5 criteria that must be met before a new institute should be established within the NIH. The Association for Research in Otolaryngology finds convincing evidence that the new institute proposed in S. 1727 fulfills these criteria.

> Criterion 1: The activity of a new institute ... must be compatible with the research and research training mission of NIH.
>
> The purpose of new institute is clearly for research and research training. No regulatory or service function is envisioned or proposed.
>
> Criterion 2: It must be demonstrable that the research area of a new institute ... is not already receiving adequate or appropriate attention.

The Association for Research in Otolaryngology believes that the arguments presented above attest fully to the inadequacy of attention being paid to the research needs of the communicatively handicapped.

Criterion 3: There must be reasonable prospects for scientific growth in a research area to justify the investment in a new institute ...
The remarkable growth over the past decade of basic science knowledge about the auditory system, about speech encoding and perception, about the receptor mechanisms involved in taste and smell, about audiovestibular neurotransmitters, about cochlear micromechanics plus the fact that there are now more scientists working in this field than ever before makes it abundantly clear that it is the growth in scientific effort and knowledge that is a major driving force for the new institute.

Criterion 4. There must be reasonable prospects of sufficient funding for a new institute ...

The President's budget for the NINCDS for FY89 is $577.1 M. Should the 19 percent of that budget traditionally allocated for Communicative Disorders be used for the new institute, its starting budget would be $109.6 M. Since overhead is traditionally estimated at 6.2 percent of the total budget, this $6.5 M would more than cover the start-up costs of the new organization.

Criterion 5. A proposed change in the NIH organizational structure should, on balance, improve communication, management, priority setting, and accountability.

The Association for Research in Otolaryngology believes that the proposed new institute will accomplish all the objectives listed in Criterion 5. Pulling the already fragmented research effort in Communication Disorders under one administration will indeed improve communication and management. Having the sole focus of the new institute rest upon Communication Disorders will facilitate priority setting. Currently, when the Director of the NINCDS must choose between allocating scarce funds for research into brain tumors, on the one hand, or for hearing disorders (which are only fatal when the victim cannot hear an alarm), on the other hand, there is a strong proclivity, when choices must be made, to fund the more life-threatening disorder rather than quality of life research.

The Association for Research in Otolaryngology appreciates the opportunity to share its views with the Committee.

STATEMENT OF

HARMON J. EYRE, M.D.

PRESIDENT
AMERICAN CANCER SOCIETY

AND

PROFESSOR OF MEDICINE AND
DIRECTOR OF CLINICAL RESEARCH,
UTAH CANCER CENTER
UNIVERSITY OF UTAH
COLLEGE OF MEDICINE

ON BEHALF OF THE
AMERICAN CANCER SOCIETY

REGARDING
REAUTHORIZATION OF THE
NATIONAL CANCER ACT

APRIL 13, 1988

AMERICAN CANCER SOCIETY, INC.
224 EAST CAPITOL STREET, WASHINGTON, D.C. 20003 202-546-4011

I am pleased to submit for the record, the position of the American Cancer Society (ACS) on reauthorization of the National Cancer Act.

The ACS is the Nation's largest Voluntary Health Agency, comprised of 2.5 million active volunteers united to conquer cancer through balanced programs in research, education, patient service and rehabilitation. The Society is organized in all 50 states, and more than 3,000 counties. In 1988, the ACS observes its 75th Anniversary, and on March 28-29, 1988 held a 75th Anniversary "Celebration of Life" in Washington, DC. Sixty Courageous Americans who have beaten cancer, representing every state in the union came to be honored by Members of the House and Senate, and the President. It was impressive. The chances are, however, if Congress had not had the foresight and wisdom it had in 1971 to write the most successful health legislation in our history, those who were honored on March 29 may not be alive today.

The 1971 National Cancer Act was unique and historic legislation. Congress freed the National Cancer Institute of bureaucratic encumbrances. It created a unique, and creative oversight/ombudsman structure to prevent, avoid, and correct stumbling blocks which traditionally have hampered efficiency and objectivity in government management. And it fixed responsibility for overseeing the new National Cancer Program at the highest level - the Executive Office of the President.

The proof of the wisdom of the Congress in passing the original National Cancer Act is clear in the continuing, increasing success in the Nation's battle against Cancer. In 1971 we were saving one in three victims of cancer. In 1988 we can proudly point to our ability to save one in two.

But progress against cancer does not come easily. While we are now able to save one in two cancer victims, the number of cancer cases in the United States is slowly rising. Success, however, does not mean we can relax. Cancer is a basic, biological phenomenon. While for many it is a disease of aging, young people become victims because it is also a disease frequently related to heredity. There are many ways to avoid and prevent cancer, but people still voluntarily do things to themselves which are almost guaranteed to induce cancer - smoking, and eating poorly are two of them. Also, people are all too often put into environmental situations where they are involuntarily exposed to carcinogens.

Progress against cancer comes in small increments, but this kind of accumulated progress, in many cases, adds to successful treatment of a previously hopeless situation; to a means of prevention of a cancer, or to the earlier detection of cancer. The result of all of these is saved lives. The progress required to make this all possible comes through research. Research

continues to create new knowledge which is applied to new ways of preventing, controlling, detecting, and treating cancer. For research to reach its most dynamic, productive potential, it must have the right environment, nourishment, and support. For cancer research, Congress has provided these essentials for the past 16 years through periodic renewals of the National Cancer Act.

The Cancer Act provides numerous authorities to the NCI, three of which the American Cancer Society believes are critical to the continuing success of the National Cancer Program, and strongly recommends be continued without change in the NCI reauthorization language:

- Presidential appointment of the President's Cancer Panel, which brings to the attention of the President any delays or blockages in the National Cancer Program;

- Presidential appointment of the NCI Director, and the National Cancer Advisory Board; and

- The authority of the Director to submit an annual NCI budget proposal directly to the President.

The latter authority allows the Director of NCI to, literally "by pass" the required procedure of other NIH Institutes. This is

one of the most practical and valuable special authorities. Other Institutes must submit their budgets for review and approval by six higher levels of bureaucracy before final funding of research and contract grants. Under the National Cancer Act, the NCI Director is authorized, each year, to submit his budget to the President with no changes by the NIH Director, the USPHS, the Assistant Secretary for Health, the Secretary of HHS, or the Office of Management and Budget. They are authorized to comment on it, but it must go, intact, to the White House.

Creation of the President's Cancer Panel was another stroke of Congressional genius. During the debate about the Cancer Act in 1971, many, including this organization, argued vigorously in favor of having the Director of the National Cancer Program report directly to the President. We argued that this was the only structure that would give the anti-cancer effort the stature it needed, and would assure that the President would be constantly aware of the dynamic needs of the cancer program. In fact, the Senate bill provided for such a structure. The House Health Subcommittee objected, however, and a solution was offered by former Congressman Archer Nelson, of Minnesota. The result was the three-person President's Cancer Panel, who, by virtue of their training, expertise, and background are exceptionally qualified to appraise the National Cancer Program.

The Panel's purpose is to monitor the Cancer Program, and to provide direct linkage between the NCI Director, the Congress,

and the President. The Panel submits progress reports to the President, the Secretary and the Congress annually.

Presidential appointment of the Director, and the 18 person National Cancer Advisory Board also has proven to be the key mechanism for obtaining the best available personnel to manage and advise the Cancer Program. The Presidential appointment of the Director allows for more independent and autonomous management of this high priority program without removing the NCI from the NIH.

It is interesting to note that occasionally officials outside of the NCI complain that the special authorities "have outlived their usefulness" or "there is no reason for them". Such remarks are not heard from individuals who know and appreciate that the dynamism of this federal program depends on the kind of freedom of operation and from bureaucratic hindrance, that so often undermines otherwise valuable programs. The American Cancer Society strongly recommends retention of these three special authorities in the National Cancer Act.

In addition to the special authorities, the ACS believes that training of research personnel is necessary to keep the pipeline of new investigators full and productive. ACS supports training authority at the highest, most flexible level.

Cancer research facilities in the U.S. are in sorry condition. In 1984 the Society, together with Dr. Armand Hammer, surveyed the construction requirements of our Nations' cancer research infrastructure; conditions then were poor. They are worse today. The Society urges Congress to continue NCI's construction authority, and provide the financial wherewithal to make it meaningful.

Also, the Society recommends that the Congress make whatever technical changes are necessary to enhance the Cancer Institutes ability to move quickly in promising directions.

The battle against cancer continues. The Congress by reauthorizing the National Cancer Act can renew their pact with the American people to maintain the fight against cancer as the highest health priority of this nation. It should happen, it must happen.

# *Report to the President's Cancer Panel on the Reauthorization of the National Cancer Act*

National Cancer Institute
April 1988

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# REPORT TO THE PRESIDENT'S CANCER PANEL ON THE REAUTHORIZATION OF THE NATIONAL CANCER ACT

## EXECUTIVE SUMMARY

In preparation for congressional hearings regarding the reauthorization of the Health Research Extension Act of 1985, Dr. Armand Hammer, Chairman of the President's Cancer Panel, requested the Director of the National Cancer Institute (NCI) to prepare this report on the special authorities and responsibilities provided specifically to the Director, NCI under Part C Subpart 1 of the Act. This Subpart is commonly referred to as the **National Cancer Act.**

ISSUE: Whether the authorities given to the National Cancer Institute under the National Cancer Act of 1971 and subsequently under the Health Research Extension Act of 1985 should be retained and/or modified.

BACKGROUND: The National Cancer Act of 1971 was designed to provide the Director, NCI with certain unique authorities to remove traditional administrative impediments in an effort to accelerate cancer research and the application of research results in cancer treatment and prevention. It recognized the need to couple authority with responsibility in programs with special priorities. Because some of these authorities have now been extended to the Director of the National Institutes of Health (NIH) and to other NIH institute directors, discussions have ensued concerning the need for the NCI to retain, in law, its special authorities.

POSITION: Cancer has been the number one concern of the American people for over 50 years. It is now the number two killer and even with a marked reduction in mortality, **cancer will become the number one killer** due to the declining mortality from heart disease of the aging population. Basic research findings paid for by NCI's investment in basic research are now voluminous and more than ever require the flexibility to transfer new technology to the public. Therefore, the National Cancer Institute firmly believes that it is critical to retain its special authorities to assure the maintenance and momentum of a coordinated, congressionally mandated National Cancer Program in an effort to reach its Year 2000 Goal of reducing cancer mortality by 50 percent. While some NCI authorities have been extended by legislation to all NIH institutes through the Secretary of the Department of Health and Human Services, the NCI still has unique authorities and responsibilities that

are vital to the National Cancer Program. Futhermore, the NCI feels that ALL of its authorities should be retained as the need to avoid as many administrative impediments as possible still exists.

**Special Authorities of the National Cancer Institute**

1. **President's Cancer Panel**

A three member, presidentially appointed panel oversees the National Cancer Program and brings to the attention of the President any obstacles adversely affecting the operations of the Institute. The law mandates that impediments to the National Cancer Program be debated in public and addressed at the highest level of Government.

Major accomplishments of the Panel include:

- has assured by its very existence, open dialogue, in public if necessary, of problems affecting the progress of the National Cancer Program. Since concerns of the NCI are, at times, also the concerns of the entire NIH, other NIH institutes also have benefitted from the Panel's access to the President and the ability to raise issues in a public forum. As a result, many issues are resolved without need of full, public Panel discussion;

- intervened on behalf of the entire NIH to assure that training authority was re-established in the 1974 authorization legislation;

- brought NIH single apportionment issue to the attention of the Office of Managment and Budget (OMB), the scientific community, and the President and was instrumental in separating congressional concern over numbers of competing grants and OMB use of the apportionment process to meet congressional grant targets. The clarification of this issue benefitted the entire NIH;

- has been the primary recommending body to the President for nominees to the National Cancer Advisory Board (NCAB) to assure Board membership without regard to political affiliation and based only on scientific/personal credentials;

- in 1975, brought to the attention of the President the need to increase the personnel ceiling for the Institute commensurate with the large budget increases received since passage of the National Cancer Act of 1971;
- performed management oversight of the 1972 conversion of

the Fort Detrick buildings in Frederick, Maryland from a facility dedicated to biological warfare, to a world-class cancer research facility;

- in 1978 led the NCI to separate the peer review process of grants from the program management of grants by consolidating the peer review system in one division and assigning the scientific management of the grant portfolios to the research divisions;

- in 1979, led the Institute to further separate program and review functions by recommending that the contract review function be separated from the contract management/scientific oversight function. Thus, all review activities were merged into a new Division of Extramural Activities thereby assuring unbiased conduct of the peer review system;

- during the period 1975-1977, the Panel recognized the need to merge the treatment activities of the Institute into one division - the Division of Cancer Treatment (DCT). For the first time, all treatment activities of NCI could be coordinated under the direction of one division; and

- in 1983 established Outstanding Investigator Grants which are awarded based on an investigator's proven career track record and not on the merits of any one specific project.

2. National Cancer Advisory Board

The NCAB consists of 18 presidentially appointed members from the scientific and lay communities. Because the Chairman is appointed by the President, the Board is able to set its own agenda and provide independent and objective advice regarding all aspects of the National Cancer Program. All other NIH research boards/councils are chaired by their institute directors.

Major accomplishments/characteristics of the Board are:

- because its members and Chairman are appointed by the President, it is more independent and able to give constructive critical advice to the Director, NCI;

- established in 1972 an extramurally managed Organ Systems Program to accelerate and target research on common tumors of major organs. The establishment of this program required the special authorities of the National Cancer Act. In 1981 the Board concluded that appropriate stimulation of the research had been accomplished and therefore, the Board subsequently recommended to internalize the program within the NCI;

- created what is now termed the "RFA" mechanism at the NIH. In 1975 the Board formulated the concept of the NCI soliciting grants to cover areas of research which were perceived to be inadequately addressed. After establishing a reserve of grant funds and identifying specific areas of science, the NCI published announcements for Cancer Research Emphasis Grants (CREG's). This mechanism was the forerunner of the Request for Grant Applications (RFA's) which is now a commonly used method of stimulating science via the grant mechanism by the entire NIH;

- the Board is able to take action on its own initiative, such as:

  a. sponsored Public Participation Hearings targeted toward involving the public in prevention and early detection activities;

  b. sponsored the Black Leadership Initiative to involve black business leaders in educating black populations concerning cancer prevention and control; and,

  c. brought to the attention of the Director, NIH the serious shortage of nursing staff in the Clinical Center and the adverse impact on the operations of the intramural NCI program;

- shortly after passage of the National Cancer Act of 1971, the Board defined the term "center" and the term "comprehensive" through establishing criteria to be used in evaluating and granting the titles "Cancer Center" and "Comprehensive Cancer Research Center;"

- participated in major reorganizations of the NCI including:

  a. the 1980 transition of the Baltimore Cancer Research Program from an intramural research program, to an independent, grant supported, university cancer center;

  b. the 1983 transfer of applied prevention activities from the Division of Cancer Cause and Prevention, to a newly created Division of Cancer Prevention and Control and the assignment of basic science preven tion research to the Division of Cancer Etiology; and,

  c. the 1982 transfer of the bioassay component of the National Toxicology Program from the NCI to the National Institute of Environmental Health Sciences (NIEHS) This transfer involved approximately $48 million and 95 positions and moved responsibility for the testing of chemicals in experimental animals for potential

carcinogenic and toxicologic effects from the NCI to the NIEHS.

3. **Presidential Appointment of the Director, NCI**

The Director, NCI is the only Presidentially appointed NIH institute director. This fact, coupled with the President's Cancer Panel, gives the Director, NCI the independent ability to vigorously pursue solutions to administrative obstacles which inhibit the scientific progress and the translation of that progress to the practice of the treatment of cancer.

4. **Professional Judgment Budget (BY-PASS Budget)**

By law, the Director submits directly to the President (OMB) a budget for the following fiscal year that will enable the Institute to pursue all scientific opportunities. This budget by-passes all internal administrative offices and informs the President directly as to the needs of the National Cancer Program. The professional judgment budget serves as the end product of an Institute-wide planning process involving Institute staff, the National Cancer Advisory Board, the President's Cancer Panel, and other expert advisors who are closest to the science and able to project the needs for an effective cancer program. The legislative provision for the By-Pass Budget was created in recognition that cancer has been the number one health concern of the American public for the past 50 years and that sufficient resources for cancer research was a public mandate. No other NIH institute has this authority.

5. **Authority to Appoint Advisory Committees**

In consultation with the NCAB, the Director, NCI may appoint advisory committees necessary to conduct the business of the Institute. Using this authority and in recognition that management of a program as large and complex as the NCI required a unique management structure, the Director has appointed and established a Board of Scientific Counselors for each research division of the Institute as well as for the Frederick Cancer Research Facility (FCRF). Each of these boards has been vested with special authorities and responsibilities unique at the NIH. By his authority under the National Cancer Act, the Director, NCI has delegated to each Board of Scientific Counselors, the authority to:

- review and approve concepts for grant or contract supported activities before issuance of a Request for Applications (RFA) for grants or a Request for Proposals (RFP) for new or recompeting contracts is allowed;

- perform peer review of the intramural research program; and

- review, comment, and advise on all aspects of both the intramural and extramural programs including financial resources.

These boards are comprised of non-Federal advisors to advise and monitor the scientific programs of the divisions and the FCRF. Through the NCI Director's authority to appoint, the membership of these boards represents a cross-section of scientific disciplines with independence of expression encouraged through the appointment of one of its members to serve as chairman.

Major accomplishments/characteristics of the Boards of Scientific Counselors are:

a. in 1976 recognized the need to provide an organized process of peer review of intramural research comparable to grant peer review for program projects (including review of laboratory/branch budgets). This highly successful process has since been required by the Health Research Extension Act of 1985 to apply to all NIH intramural programs;

b. The Boards of Scientific Counselors review both the intramural and extramural activities of NCI's divisions and therefore can judge and advise on the balance of resources between intramural and extramural programs -- advice not only useful to the divisions, but also to the NCAB and the Institute as a whole. This oversight of the total scientific content of both intramural and extramural research is unique to the NCI and is possible only because of the NCI authority to establish and appoint appropriate members to such committees. Furthermore, it assures that the extramural and intramural programs are complementary and that the resources available to the Institute are utilized in the most effective manner possible;

c. the Boards of Scientific Counselors, in conjunction with the NCAB and the President's Cancer Panel, form a network of advisory committees to the Institute that comprise an infrastructure making possible the governance of science. Through the close relationship between the President's Cancer Panel, the National Cancer Advisory Board, and the divisional Boards of Scientific Counselors, the overall direction, goals, and priorities of the National Cancer Program and National Cancer Institute become matters of public debate and discussion.

For example, in 1985, the Division of Cancer Treatment recommended that the NCI Drug Development Program be restructured from a system using live animals as an initial

screen for potentially active compounds, to a system based on human tumor cell lines. This represented a major scientific change. Intensive discussion and debate took place both at the DCT Board of Scientific Counselors as well as at the National Cancer Advisory Board and was reported to the President's Cancer Panel. Through these discussions, changes in staff proposals were adopted with the general recognition that the change would have far reaching ramifications on the development of cancer chemotherapy for decades.

The NCI is convinced that its authority to establish and appoint advisory committees to work in harmony with the Panel and NCAB, is the heart of its ability to conduct business in an open, constructive environment and represents the foundation for free scientific debate and discussion concerning the allocation of scarce resources.

The National Cancer Act, as ircorporated in the Health Research Extension Act of 1985, contains many other important special authorities for the National Cancer Institute. This summary has highlighted only the most significant and visible of these authorities, and omission should not be interpreted as insignificance. The attached full report describes the above authorities in more detail as well as numerous others which have served the NCI and American public well in the goal toward the conquest of cancer.

# I. INTRODUCTION

For 50 years cancer has been the number one health concern and the second leading cause of death for the American people. Even if NCI achieves its stated goal of decreasing the cancer mortality rate by 50 percent by the beginning of the next century, cancer will become the nation's leading cause of death due to the aging of the population and the declining mortality from heart disease. The public fear of cancer, the perceived failure of the Government to have given its control sufficient priority, and concern that a special initiative on cancer would be met with resistance within the bureaucracy led to the passage of the National Cancer Act in 1971 and to its renewal and amendments in the years since.

In November 1987, in anticipation of the 1988 reauthorization of the National Cancer Act, Dr. Armand Hammer, Chairman of the President's Cancer Panel, directed the National Cancer Institute (NCI) to prepare a report on the impact of the Act and its amendments on progress in cancer research. He asked that this report include:

1. a concise history of the National Cancer Act;
2. a description of the special authorities provided by the Act;
3. how the Act and its amendments have been able to expedite progress in cancer research and treatment;
4. whether any eliminated authorities should be restored;
5. whether any new authorities are needed in 1988 to guarantee the highest quality National Cancer Program; and,
6. the funding deemed necessary to support the National Cancer Program for the next five years.

The body of this report addresses these requests. The Appendices supplement the document with the following materials: 1) a discussion and wording of recommended legislative changes for 1988; 2) a summary listing of authorities given to NCI by the National Cancer Act that have since been extended to other NIH components; 3) examples of President's Cancer Panel activities; 4) examples of National Cancer Advisory Board activities; 5) examples of collaboration with other Federal agencies; 6) examples of public information activities; 7) a 1984 case study of the National Cancer Institute commissioned by the Institute of Medicine as part of its study of the organization of the National Institutes of Health (NIH); and 8) the 1971 Summary of the Report of the National Panel of Consultants on the Conquest of Cancer.

## The National Cancer Act of 1971

In 1937, responding to the concern of the American people about cancer, the U.S. Congress created the National Cancer Institute as a division of the United States Public Health Service. NCI was moved in 1944 to the National Institutes of Health. NCI was the first categorical disease institute and served as the prototype of this structure at NIH.

In 1970 Senator Ralph W. Yarborough, Chairman of the Senate Labor and Public Welfare Committee, introduced a resolution, supported by 53 of his Senate colleagues, calling for a study of the status of cancer research. Consequently, the Senate authorized the formation of the **National Panel of Consultants on the Conquest of Cancer**, a committee composed of 26 eminent laymen and scientists. The panel's report, **A National Program for the Conquest of Cancer** (Appendix 8), became the blueprint for the development of the National Cancer Act with the special authorities it provides the NCI to coordinate, expand and expedite cancer research.

The report's bold recommendations called for a new agency reporting directly to the President of the United States with greatly expanded resources of manpower, facilities, and funds to conquer cancer. The resulting legislation represented a masterful compromise, reached after months of public discussion and debate, regarding how best to accelerate progress in cancer research and its application and yet preserve scientific ties within the NIH community. This legislation has governed the relationship of NCI to NIH and other agencies for 16 years. Its durability is a testimony to the wisdom of the architects of the Act.

The Panel of Consultants (the Yarborough Committee) concluded in 1970 that:

> **the National Cancer Institute has done excellent work itself and has supported grants and contracts in the scientific community, which have resulted in much outstanding work, but the overall research effort is fragmented and, for the most part, uncoordinated. The effort in cancer should now be expanded and intensified under an effective administration charged with developing and executing a comprehensive national plan for the conquest of cancer at the earliest possible time.**

The Panel of Consultants laid out three necessary ingredients for the success of an amplified National Cancer Program: **effective administration; a comprehensive and coordinated national plan of action; and the necessary financial resources.**

Discussion ensued within congressional and scientific quarters regarding whether it would be possible and beneficial to "plan" in a scientific environment; whether the current state of knowledge about cancer warranted such an adventuresome program; and whether increased resources for cancer research would jeopardize other areas of health research. The latter was the most worrisome, and this concern turned out to be unfounded.

In a paper written on the occasion of the fifteenth anniversary of the Act, Benno Schmidt, the Chairman of the Yarborough Panel of Consultants and the first Chairman of the President's Cancer Panel, (1971 to 1980) noted that **during the 1970's the NCI budget had risen**

from $180 million in 1970 to over $1 billion in 1980 and that during the same period the NIH budget had grown from $1 billion to $3.429 billion, "thus belying the fear so widely expressed in 1970 and 1971 that any increase in the cancer budget would be at the expense of other institutes. Since 1980, the appropriations have increased annually so that by 1986 the NCI budget had reached $1.2 billion and the NIH budget was $5.3 billion.....permitting levels of fundamental biomedical research that were totally unprecedented." (1) Over two-thirds of the cancer program money was spent on basic biomedical research. Figures 1, 2 and 3 show the relative increases for the individual NIH Research Institutes. While increases to the NCI budget were the highest of all the institutes from 1970 to 1979, the rate of growth of the NCI budget slowed considerably and was surpassed by that for all the other institutes between 1980 and 1988.

In 1977, the Director of NIH, Dr. Donald Fredrickson, wrote in a memorandum to the Office of the Assistant Secretary for Health "almost six years after enactment of the special cancer legislation, it is fair to say that few of the predicted problems have materialized, and those not to the extent predicted." Commenting on the four-fold increase in funding that had occurred by 1977, Dr. Fredrickson concluded that the "increase in funding had been extraordinarily well managed."(2)

By far, the most controversial of the National Panel of Consultants' recommendations was the plan to remove the National Cancer Institute from the NIH and the Department of Health, Education and Welfare (DHEW), the predecessor to the current Department of Health and Human Services (DHHS). The impetus for this initial recommendation derived from the Yarborough Committee's strong feelings about the need for an organization designed for action. The Panel of Consultants noted:

> An effective major assault on cancer requires an administrative setup which can efficiently administer the coherent program that is required in this formidable and complex scientific field. Such a setup will not be easy to achieve within the Federal Government. The effective implementation of such a program will require a simplification of organizational arrangements and a drastic reduction in the number of people involved in administrative decisions. This type of straight-line organizational efficiency does not exist today in the National Cancer Institute, the National Institutes of Health, or the Department of Health, Education, and Welfare ... there is real doubt whether the kind of organization that is required for this program can in fact be achieved within the NIH or the DHEW.

The need for a compromise was seen by all, including the Yarborough Committee and its Senate supporters, when intense opposition to elevating the NCI to an independent agency, separate from the NIH, threatened to jeopardize all of the Panel's recommendations.

Representative Ancher Nelson from Minnesota solved the dilemma by suggesting that Congress create a three-person President's Cancer Panel, appointed by the President, to supervise and monitor the National Cancer Program and to report directly to the President any delays or blockages in its rapid execution as well as on progress. Further, the NCI would have a "budget bypass" which would permit the Institute, with review by the National Cancer Advisory Board, to submit its budget directly to the President without change by the NIH and the Department.

This compromise was struck by providing special authorities to NCI, while leaving it within NIH, and by creating an enhanced and accelerated National Cancer Program. On December 23, 1971, President Nixon signed the National Cancer Act of 1971 into law.

The Cancer Act mandated that NCI pursue basic research and take responsibility for the application of the results of that research in an organized program to reduce incidence, morbidity and mortality from cancer. The mandate to apply the results of basic research necessitated authorization for special programs and the ability to undertake initiatives not traditional for an NIH institute. Congress gave the clear signal that the NCI was to move ahead on all fronts with minimal interference from higher levels in the bureaucratic structure.

## II. THE SPECIAL AUTHORITIES OF THE NATIONAL CANCER ACT

The special authorities of the National Cancer Act and its subsequent amendments fall into three major categories: strengthening the National Cancer Program's access to the President; facilitating an expedited cancer program; and expanding existing programs.

Although the NCI legally could have carried out some activities such as training, information dissemination, constructing or leasing facilities, and appointing advisory committees, all such activities had been severely limited by higher level policy or had failed to develop at the Institute. The Act mandates that activities such as information dissemination and training be developed and allowed to proceed. Other special authorities assured that the NCI would create a national program with as wide an impact as possible.

The Act remains essentially intact, and no major authorities have been deleted during the past 16 years. However, minor modifications would assist the Institute in meeting its responsibilities or clarify existing authorities, and are discussed in this report and detailed in Appendix 1. Congress considered a number of authorities so useful to NCI and NIH that the Health Research Extension Act (HREA) of 1985 extended them to other components of NIH as well (Appendix 2). Others remain unique to NCI.



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Two points relative to reauthorization of the Cancer Act deserve emphasis. As the architects of the Act had hoped, the biologic revolution, fostered by the infusion of resources that followed passage of the legislation, has created unprecedented opportunities to apply the results of the new biology to reduce incidence, morbidity and mortality from cancer. Special authorities are necessary, especially in the current NIH climate, to couple responsibility for a program of the size and scope of the National Cancer Program with the authority to fulfill the dual mandate to support basic research and to apply rapidly the results of research to decrease the incidence, morbidity, and mortality of cancer.

## A. Strengthening Access to the President

### President's Cancer Panel

This three-member Panel, appointed by the President, with the Chairman named by the President, is charged "to monitor the development and execution of the National Cancer Program... and report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President."

The Panel is required to submit progress reports to the President, as well as an annual evaluation of the efficacy of the National Cancer Program, including recommendations, to the President, the Secretary and the Congress. The Panel also advises the President on the selection and performance of the Director, NCI and plays an essential role in identifying and advising the President on candidates for the National Cancer Advisory Board.

The statutory requirement that the Panel immediately report to the President delays or blockages in the rapid execution of the National Cancer Program also makes it incumbent upon the Director, NCI to report such problems to the Panel. An important consequence of the existence of the Panel and the requirement of the Federal Advisory Committee Act that it hold its meetings in public to discuss impediments, solve problems and review priorities, is that dialogue is often stimulated at all levels of government and in the private sector. This promotes early resolution of problems that might otherwise have required actual Panel discussion.

Throughout its existence the Panel has monitored problems faced by the National Cancer Institute and NIH and intervened when necessary on subjects such as budget, staffing levels, the grant and contract review process, and the cancer centers program. (Appendix 3)

### National Cancer Advisory Board

The National Cancer Act of 1971 replaced the National Advisory Cancer Council, a standard research institute council, with the National Cancer Advisory Board (NCAB). Its 18 members would now be appointed by the President from the scientific and lay communities, with ex-

officio members (now 11) from other Federal agencies with responsibilities related to cancer research, and therefore part of the National Cancer Program. Unlike advisory councils for the other NIH institutes and the Office of the Director, NIH which are appointed by the Secretary and chaired by the Institute Director, the Chairman of the NCAB is selected by the President from among the appointed members, which promotes more objective advice and review. Until the 1985 amendments, the law specified that the ex officio members were non-voting. Removing this stipulation has resulted in voting status for the 11 Federal ex officio members.

In addition to the customary role of NIH councils in the review and approval of grants, the NCAB was authorized to hold public hearings and to investigate programs and activities of the National Cancer Program. In doing so, the NCAB has played a significant role in establishing and restructuring major programs such as: developing the initial criteria for comprehensive cancer centers and later modifying them as necessary, the Organ Site Program, the Biological Response Modifiers Program and, most recently, the NCI's program of AIDS research. The 1985 HREA provided similar authorities to other NIH councils.

The NCAB advises on policy and resource allocation and reviews in detail the development of the By-Pass Budget. All major initiatives which affect the entire Institute or the Cancer Program are first brought to the NCAB for advice and guidance. A number of these are discussed in Appendix 4.

**Recommended legislative changes:**

Restore the provision that ex officio members are non-voting to preserve the authority of the presidential appointees.

Add an ex officio member from the Department of Energy, which did not exist at the time the Act was passed, and which supports cancer-related research activities.

**Presidential Appointment of the Director, NCI**

As part of the legislative compromise which kept the NCI within the NIH, but provided it special autonomy, the National Cancer Act specified that the NCI Director should be appointed by the President. This indicated the priority of the National Cancer Program and the need for the Institute Director to have independent authority. To preserve the relationship at NIH, the Act also made the Director, NIH a presidential appointee and specified that the Director, NCI should report to him in all matters except budget.

The exclusion of budget matters was deleted in the 1985 HREA.

**By-Pass Budget - the Professional Judgment Budget**

The NCI was required to submit an annual budget to the President developed on the basis of scientific opportunity after consultation with the National Cancer Advisory Board, but without modification at other levels in the Executive Branch. This provision is unique to NCI and is also a result of the decision of the authors of the National Cancer Act to keep NCI within NIH, while providing special autonomy as though it were an independent agency. Direct submission allows the President and the Congress to consider NCI funding priorities in the light of the professional judgment of both lay and scientific advisors who are closest to cancer research advances. The By-Pass Budget is also used by the Panel in advising the President.

The By-Pass Budget is a clear statement not only of the level of funding which could be productively utilized, but of priorities. In recent years, the National Cancer Advisory Board has directed that the need for support for construction and renovation of biomedical research facilities be clearly articulated in the By-Pass Budget.

NCI simultaneously develops a budget within the NIH structure for submission, through the Department, to the Office of Management and Budget (OMB). NCI develops its initial request to the Department based on the By-Pass Budget priorities. However, this request is often altered at NIH, the Department, and OMB.

The By-Pass Budget also serves as a planning document, as it results from a forward planning process used by the NCI since 1980. Since 1984 when the Institute announced the Goal for the Year 2000 of reducing cancer mortality rates by 50 percent by applying what is now known about cancer prevention, early detection and treatment, the By-Pass Budget has served as the document which links resource requirements to attaining this goal. (3)

Optimum funding to operate the National Cancer Program for the next five years is shown in the By-Pass Budget requests for FY 1989 through FY 1992.

**BY-PASS BUDGET REQUEST**
**FY 1989 - FY 1993**
**(in Thousands)**

| | Cancer Research | Cancer Prevention and Control | Total |
|---|---|---|---|
| FY 1989 | $1,968,629 | $111,371 | $2,080,000 |
| FY 1990 | $2,169,000 | $135,000 | $2,304,000 |
| FY 1991 | $2,454,000 | $155,000 | $2,609,000 |
| FY 1992 | $2,702,000 | $175,000 | $2,877,000 |
| FY 1993 | $2,924,126 | $200,000 | $3,124,126 |
| | **President's Budget Request** | | |
| FY 1989 | $1,396,978 | $ 71,278 | $1,468,256 |

The Act required that NCI submit its budget request to the President and that it receive, directly from the President and the Office of Management and Budget, all funds appropriated by Congress for obligation and expenditure by the Institute. The 1985 HREA permitted, but no longer required that funds be apportioned directly to NCI.

In 1985, OMB pooled all NIH funding into one centralized apportionment tied to funding mechanisms, a dramatic change from the past when funds were apportioned to each Institute. OMB made this change in response to a congressional mandate to fund a specific number of new and competing grants, stimulated by the 1979 initiative of the NIH Director to stabilize support for research. (4) This single change resulted in a marked decrease in flexibility in the day-to-day management of research resources, especially deleterious for an institute of the size and breadth of NCI. Had the language of the original Act, requiring that NCI funds be received directly by the Institute been retained, it would not have been possible for OMB to consolidate the entire NIH apportionment.

The requirement for a fixed number of grants, without the necessary funds to support them, finally resulted in awards so markedly below recommended levels, that it, in essence, negated the value of peer review judgment. Recognizing this, the President's Cancer Panel, and the National Cancer Advisory Board, intervened in 1986 on behalf of the NIH and NCI. Congress, as a result of these and others' efforts, has not since required a fixed number of grants in law and, in turn, OMB has reverted to the former apportionment process.

**Recommended legislative changes:**

Authorize appropriations at the levels requested in the By-Pass Budget.

Restore the original language of the National Cancer Act stating that the Director, NCI **shall** receive directly all funds appropriated to the Institute, replacing the current **"may"** with "shall."

## B. Facilitating an Expedited National Cancer Program

### Authority to Appoint Advisory Committees

The Congress recognized that the Director, NCI had been charged with a large and complex mission and had to be able, independently, to appoint advisors based on his own assessment of program and scientific need. The National Cancer Act therefore permits the Director, NCI, to appoint advisory committees composed of private citizens and officials of Federal, State and local governments.

This authority is used to appoint **Boards of Scientific Counselors (BSCs)** to the four program divisions of the NCI and the **Frederick Cancer Research Facility (FCRF) Advisory Committee**, as well as other

advisory committees when needed. The function of these advisory bodies is unique to the NCI at NIH and forms the basis for the governance of science in the cancer program and NCI's planning process. This is discussed more fully below.

The Boards of Scientific Counselors review extramural and intramural research and must approve all extramural research initiatives of an NCI division. They also conduct regular site visits of the intramural programs with written documentation, including budgets, analogous to the review of extramural program project grants. Their advice is critical in decisions concerning priorities, resource allocation, promotions, and reorganizations.

NCI's intramural site visit process, with its display of budgets, has been received with enthusiasm by the extramural community. As a result, the HREA of 1985 requires the Director, NIH to establish procedures for review of research at the NIH. This requirement is modeled on the NCI process. The NIH Legal Advisor has interpreted the 1985 Act to permit NCI to continue to use advisory committees appointed under its own authority, rather than the NIH Director's authority, to conduct the now mandated intramural reviews, but the language is unclear.

**Recommended legislative change:**

The reauthorization should specify that advisory committees appointed under the authority of the Director, NCI may conduct the required peer review of the NCI intramural program.

Peer Review Authority

Congress required NCI to provide for scientific peer review of its research grants and programs. This was to assure that NCI would fund projects of high merit and that activities authorized by the Act, but atypical for the rest of the NIH, would receive expert peer evaluation. Authority to establish peer review groups permitted the creation, in 1972, of the unique Organ Site Program, now the Organ Systems Program, with its own authority to review grants.

Prior to 1985, establishment of scientific peer review groups by the Director, NCI required approval of the Director, NIH and the NCAB. HREA extended authority for peer review of extramural research to all NIH institute directors. However, HREA required that **appointment** rather than **establishment** of peer review groups be approved by the advisory council of an institute and the Director, NIH. This could be construed to mean that the appointment of individual members requires approval. It would be inappropriate for the NCAB to approve the appointment of individual members of peer review committees for which it is the second level reviewer.

**Recommended legislative change:**

Clarify that the requirement for approval of the NCAB and the Director, NIH applies only to the establishment of peer review committees, but not to appointment of their members.

Construction Authority

Although construction authorities had existed at the NIH since 1948, they had become inactive or had been transferred elsewhere within the Public Health Service by 1968. The National Cancer Act of 1971 provided NCI with both intramural and extramural construction authority, making it the only NIH research institute with such authorities. The 1974 amendments clarified that this authority was for basic, as well as clinical, research facility construction and could include construction of biohazard and animal facilities. Extramural construction authority subsequently has been provided to two other institutes. An NIH committee, recently convened in response to a Senate directive, has recommended that authority also be given to the NIH for a general extramural construction program. Construction grants are awarded through the peer review system based on the scientific merit of the research to be conducted in the facility.

Construction authority supported the development of cancer research facilities across the country and has had a remarkable impact on the ability to attract private sector support for construction projects. Construction grants initially required 25 percent matching funds, later changed to 50 percent. NCI construction grants of $208 million generated $205 million of matching funds between 1972 and 1980. The authority has also enabled the NCI to modernize its own facilities. In the period 1972 to 1987, the NCI expended $299,268,097 for construction: $246,682,509 or 82 percent was awarded for extramural grants and contracts while $52,585,588 or 18 percent was spent on the Bethesda campus and at the Frederick Cancer Research Facility.

Construction authority enabled the NCI to utilize fully the facilities at Fort Detrick, Maryland that President Nixon transferred from the Department of Defense to NCI. Today the Frederick facility houses special containment laboratories for virus research, including research on AIDS; a modern fermentation facility to produce anti-cancer agents for clinical evaluation and analysis; and the only supercomputer facility in the United States dedicated solely to biomedical research. The NCI construction authority and associated funds remain the only means by which the NCI can maintain the physical plant at the Frederick Cancer Research Facility.

In recent years, appropriations for cancer research facility construction have been much more modest. Nevertheless, an NCI construction grant places a peer review seal of approval on a project which declares it to be a "winner," facilitating fund raising. Recently, grantees have successfully raised matching funds which exceeded NCI awards by as much as nine to one.

## Authority to Award Contracts

The National Cancer Act of 1971 gave the Director, NCI independent authority to enter into contracts for research. The need for this authority was documented in a 1970 Government Accounting Office (GAO) report, requested by Senator Yarborough, that reported delays due to duplicate reviews by the NIH. The new authority made it possible to award contracts more rapidly. Contracts have served as a means to launch a research effort when speed is important. NCI has used the contracting authority to act quickly on priority programs as exemplified by; the establishment and operation of the Frederick Cancer Research Facility including the supercomputer facility, the International Cancer Research Data Bank (ICRDB), the Surveillance, Epidemiology and End Results (SEER) Program, the Physician Data Query (PDQ) system, the Chemoprevention Program, the Smoking, Tobacco and Cancer Program and NCI AIDS efforts in drug and vaccine development. The contracting authority was also used to expand rapidly such programs as the Virus Cancer Program, the Cancer Drug Development Program, the Clinical Trials Programs (treatment and prevention trials) and the Chemical Carcinogen Bioassay Program.

An NCI-sponsored study to evaluate the mechanisms that supported major research advances, showed that contracts have played a significant role in some phase of almost all of the major basic and clinical advances, as identified by an expert advisory panel. Contracts also have proven useful in stimulating research effort in a particular field to a level sufficient to generate support through investigator-initiated grants. (5)

The Director, NCI also uses his contracting authority to issue Contracting Officer Warrants which allow a contracting officer to award contracts and to authorize advance payment to a contractor as necessary. The National Heart, Lung and Blood Institute also has received its own contracting authority, but all other Institutes receive contracting authority through a delegation from the Secretary, DHHS.

## Award of Small Grants

In 1971, the Congress gave the Director, NCI the authority to award grants up to $35,000, and since 1985 up to $50,000, after peer review, but without review and approval by the National Cancer Advisory Board. This has allowed the NCI to expedite the award of small grants, often used to fund first-time and minority awardees and special programs to stimulate prevention research, including small grants programs in epidemiology and cancer prevention.

This authority has since been extended to other NIH institute directors.

Authority to Hire Expert Consultants

The National Cancer Act of 1971 gave the NCI Director, in consultation with the NCAB, special authority to hire experts (originally 50 and currently 151) without regard to employment ceilings or certain Civil Service requirements. This mechanism allowed quick expansion during the 1970's and the employment of people with selected skills for specific program needs who would not necessarily become permanent staff. The effectiveness of this mechanism led the NIH to request and receive a similar authority in the mid-1970's. It has also specifically been provided to the National Heart, Lung and Blood Institute.

In 1982 the Office of Management and Budget, contrary to congressional report language, required that experts be counted against employment ceilings. A one-time ceiling increase was provided to the NCI for the 114 experts employed at the time, but not the 151 authorized, thus reducing flexibility in using this authority. NIH would benefit as a whole if Congress stated in law that expert consultant appointments are not to be counted against employment ceilings, allowing use of these appointments to be managed within available budgets.

The 1971 Act required the Director, NCI to consult with the NCAB in exercising this authority. In 1985 the law was changed to require that the NCAB approve expert consultant appointments. The NCAB has expressed the opinion that approval of individual temporary personnel appointments is not an appropriate Board role.

Recommended legislative change:

Restore the consultative rather than approval role of the NCAB for expert appointments.

Mandate to Expand, Intensify and Coordinate Federal and Non-Federal Cancer Research

The National Cancer Act of 1971 and subsequent amendments directed the NCI to plan and develop an expanded, intensified and coordinated cancer research program encompassing the programs of the NCI, related programs of the other NIH research institutes, and other Federal and non-Federal programs. The Congress used the word shall in describing such a role, requiring the NCI to develop a true national program. Responsibility for the coordination of a national program is not a traditional NIH mission. Simultaneously, the NCI was authorized to utilize, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies.

Federal Coordination Since 1971, the NCI has developed important working agreements with a large number of other Federal agencies with activities relevant to the National Cancer Program. It currently supports activities through interagency agreements with 16 other

Federal organizations. (Appendix 5)

**Collaboration with State and Local Governments** In the early 1970's the Institute worked with State and territorial health departments on programs to reduce radiation exposure from mammography and promote screening for cervical cancer. Today, NCI provides technical assistance and grants to State health departments to expand capabilities and help them use their own funds most effectively for cancer prevention and control and address specific local and regional cancer problems. As more State legislatures develop cancer plans, the NCI advises them regarding effective strategies and maintains a central information resource on State and local cancer legislation.

Mandate to Collaborate with Private Industry

In a prescient move, the original National Cancer Act and all amendments have directed the NCI to encourage and coordinate cancer research by industry. NCI contracts for cancer drug development in the 1960's established the precedent at NIH for encouraging collaboration with private industry. The Institute developed commercial discreet agreements to protect proprietary rights to agents submitted for testing at NCI, and was given authority to use an "alternate patent clause" which allowed companies to obtain patents for work done with Government support, while preserving Government "march in" rights to develop resulting drugs should industry fail to do so. Such arrangements have been codified in law with the passage of the Stevenson-Wydler Act.

NCI collaborates with industry in cancer and AIDS drug screening, and development and conduct of clinical trials. NCI's drug development program, unique at NIH, has been involved in some phase of the development of almost all currently available anti-cancer drugs. It was the model for the AIDS drug development program, also managed by NCI, which has developed azidothymidine, dideoxyadenosine, dideoxyinosine and dideoxycytidine for the treatment of AIDS.

Mandate to Develop and Update a National Cancer Plan

Congress recognized that along with the new authorities provided by the 1971 Act, there would be a large influx of new monies, often for activities uncommon at NIH. Therefore, it required the development of a National Cancer Plan to be updated annually. The National Cancer Plan listed areas of scientific investigation thought to be key to eradicating human cancer. Its development and publication attracted more scientists with diverse interests to cancer research.

In 1980 the National Cancer Institute established integrated Institute-wide mechanisms for executive management and advisory structures to carry out its mandate through the day to day management of the Institute. The Institute's system of boards, described below, and the NCI Executive Committee conduct the annual planning process. Priorities and associated resource allocations are expressed in the

annual By-Pass Budget which includes projected requirements for a total five year period.

In 1985, Congress deleted the requirement for annual five year plans and asked for a biennial report from the entire NIH for which NCI prepares a section.

Authority to Accept Unconditional Gifts

The 1971 National Cancer Act authorized NCI to accept unconditional gifts, such as donations of money and property. The NCI Gift Fund can be used to support any activity for which the Institute is authorized to use appropriated funds and provides a valuable resource for special projects.

In 1985, this authority was extended to all the directors of NIH Institutes.

Authority to Accept Voluntary and Uncompensated Services

In addition to the authority to accept gifts, the 1971 Act permitted the Director, NCI to accept volunteer services.

In 1985, this was extended to the Directors of all NIH Institutes.

C. Program Expansion

Mandate to Conduct Cancer Control Activities

Congress has always been intent on assuring that the results of cancer research are translated rapidly into prevention and treatment benefits for the public. NCI's 1937 authorization included cancer control activities. However, in 1957 State cancer control activities were transferred to the Public Health Service Bureau of State Services and cancer control programs at the NCI ceased. In 1965 cancer control was moved to the new Regional Medical Program, and by 1970 no cancer control programs were sponsored by the Federal government.

The 1971 National Cancer Act explicitly mandated cancer control, which forms the bridge between new knowledge gained from research and the application of that knowledge to the prevention, early diagnosis and treatment of cancer. Funding for cancer control was to be considered separately from the competition for basic research dollars. This separation was described as a most useful provision in the previously cited Fredrickson memorandum.

NCI's cancer control programs provided a prototype for the 1977 NIH initiative to develop demonstration, education, and technology transfer activities in the new Office of the Medical Application of Research, which includes the Consensus Development Conferences. However, NCI is the only NIH component with a separate budget line for control activities.

The cancer control programs are now used as the effector arm for applied prevention research and the cancer control budget is the source of funding for:

the **Smoking, Tobacco and Cancer Program**, which supports studies of smoking prevention and cessation methods involving 10 million Americans;

the **Chemoprevention Program**, which identifies micronutrients which may be able to inhibit or reverse the promotion stage of carcinogenesis and includes 24 clinical trials of the ability of micronutrients to reduce cancer incidence, with an additional 14 trials soon to begin;

the **Diet, Nutrition and Cancer Program**, which seeks to understand how diet is related to cancer, and to learn how to modify diets to reduce cancer risk;

the **Early Detection Program**, which promotes full utilization of effective early detection and screening technologies and collaborates with the American Cancer Society in the development of scientifically sound national screening recommendations;

the **Community Clinical Oncology Program**, which attempts to improve the effectiveness of cancer detection, treatment, prevention and rehabilitation at the community level; and

the **Cancer Control Science Program**, which supports intervention research on effective applications of existing knowledge, research to reduce the cancer burden in special populations, training for professionals in prevention and control activities, and large grants for **Cancer Control Research Units** and **Cancer Control Science Programs**.

Authority to Establish National Cancer Research and Demonstration Centers

During its deliberations in 1970, the National Panel of Consultants on the Conquest of Cancer was impressed with the contributions made by the three existing comprehensive cancer centers and NCI's research at the NIH Clinical Center. It determined that **"the comprehensive cancer center offers the best organizational structure for the expanded attack on cancer."** Consequently, the Panel recommended that

> **Existing cancer centers should be strengthened and additional cancer centers in different parts of the country should be created...In addition to the few comprehensive cancer centers that exist in the United States today, there are a number of other institutions which combine all or most of the capabilities for a multidisciplinary effort in cancer. These could serve as a base for the creation of additional centers...**

The National Cancer Act authorized the Director of the Institute to "pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for cancer."

The major intent of the Congress in establishing the Cancer Centers Program was to erect a nationwide structure to promote these ends. Today, the United States has 60 comprehensive, clinical, laboratory, and consortium centers which are a unique national resource and compete successfully for about half of the research and training support awarded annually by NCI.

Mandate to Enhance and Expand Information Dissemination

The 1971 Act authorized the Director, NCI "to take necessary action to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the NCI and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally."

While the original Act authorized NCI information dissemination, this activity proved controversial and was often impeded. The Congress therefore explicitly required information dissemination programs for the public, health professionals and the scientific community in the 1974 Amendments. Congressional reports accompanying those amendments made it clear that it was the intent of the House that "the new authority and its exercise by the NCI should not be restricted or curtailed by HEW." The Senate report stated that

> The Committee is concerned about the loss of the independent authorities of the Director, NCI, to conduct a full range of communications, information and public affairs activities in support of the National Cancer Program. These authorities are important to the effective implementation of the Act, and are not to be subject to regulation or modification within DHEW.

Since 1974, the Department has honored the intent of Congress, and has not required clearances for NCI information programs.

Because of the strong legislative mandate and the attendant flexibility, NCI, through its Office of Cancer Communications, has a strong integrated information program for patients and the public which has gone from distributing a few thousand copies of educational materials in 1974 to responding to 600,000 inquiries in 1987 and distributing 20 million pieces of public and patient education materials in 1987. (Appendix 6) The legal requirement that all printing be contracted through the Government Printing Office (GPO) has resulted in delays in printing education materials. Actual costs are sometimes far in excess of estimates, making it difficult to manage the printing budget.

**Recommended legislative change:**

Remove the legal requirement that NCI use the Government Printing Office as the agent for all commercial printing and typesetting to promote speed, and potentially reduce costs. Congress has exempted the National Science Foundation from this requirement.

International Cancer Research Data Bank

The International Cancer Research Data Bank (ICRDB) was mandated in the 1971 Act which required it to collect, catalog, store and disseminate, insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research throughout the world. Today, information services for investigators and medical practitioners are consolidated in the International Cancer Information Center (ICIC) including:

A. the **CANCERLINE** computer database, which contains:

**CANCERLIT**: which contains approximately 600,000 citations/abstracts of cancer literature, updated monthly;
**CLINPROT**: which contains detailed summaries of investigational clinical cancer therapy protocols in the U.S. and other countries;

B. three series of publications with over 24,000 subscribers;

**CANCERGRAMS**: monthly publications with 65 different series in Diagnosis and Therapy, Carcinogenesis, and Basic Cancer Biology, listing 30 to 100 abstracts in each issue;

**ONCOLOGY OVERVIEWS**: 15 specialized bibliographies per year with abstracts and an editorial commentary on selected area of cancer literature; and

**RECENT REVIEWS**; three issues a year which compile abstracts of 250 to 400 review articles on cancer research.

C. the **Physician Data Query (PDQ)**, which was completed in 1984 utilizing the authorities of the Act, facilitates transfer of advances in cancer treatment to clinical practice through an online database available through the National Library of Medicine and private information vendors. Updated monthly, it provides state-of-the-art treatment statements for almost all cancers, geographically matrixed information on over 1,000 investigational clinical protocols open for patient referral, names of physicians specializing in cancer treatment as well as hospitals with organized cancer programs; and

D. the **Journal of the National Cancer Institute**, which is a bi-weekly publication read by about 10,000 investigators, and is dedicated to the rapid publication of both clinical and basic

cancer research reports.

Special Training Authority

The 1971 National Cancer Act, building upon efforts begun in 1938, mandated support for training programs in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base for participation in clinical and basic research and treatment programs relating to cancer, including, where appropriate, the use of training stipends, fellowships, and career awards. Other NIH Institutes were authorized to support research, but not clinical training.

The Act authorized clinical training programs for health professionals including training in "advanced diagnostic, prevention and treatment methods," thus assuring an adequate supply of trained cancer specialists. These programs are a significant part of NCI's network for the application of the results of research. Since 1971, through training funds provided by NCI, pediatric and medical oncology were established as new specialties and their numbers grew from fewer than 100 to over 4,000; likewise, the number of radiation oncologists grew from a few hundred to 1,500.

In response to an Administration decision that all federally funded research training activities were "not appropriate," and should cease, Congress passed the National Research Service Act (NRSA) of 1974 which is the authority for all NIH extramural research training. The 1974 Amendments to the National Cancer Act also reinforced the authority of the Director, NCI to support clinical as well as research training and allow the Institute flexibility to restructure its training programs to meet evolving needs.

NCI training authorities are used to target training efforts in high priority areas which are not covered under the NRSA or the general NIH research training authority and to support specialized intramural training activities.

The NCI Cancer Education Program, which originally was used to support the development of oncology curricula in health professions schools, is now used to support:

training for doctoral level practitioners in chronic disease prevention and control, emphasizing cancer;

short research experiences for health professions and minority students;

the development and implementation of nutrition curricula for health professions schools; and

selected short courses to meet identified needs.

Other special training programs which NCI is able to conduct under the authorities provided by the Act include:

the **NCI Student Research Training Program**, which provides training in NCI laboratories for high school, college and graduate students;

the **Biotechnology Fellowship Program**, which supports postdoctoral training in the clinical application of biotechnology;

the **Cancer Nurse Training Program**, which trains nurses in the care and treatment of cancer patients in a clinical research setting, addressing the critically short supply of trained oncology nurses; and

the **Cancer Prevention Training Program**, which trains scientists and other professionals to conduct cancer prevention research and meet the need for State and local health agency cancer control staff.

Foreign Research and Training

The National Cancer Act of 1971 required the NCI to support cancer research outside the U.S. by highly qualified foreign nationals; collaborative research involving American and foreign participants; and the training of American scientists abroad as well as foreign scientists in the U.S. As a result of this mandate, the NCI awards research grants to leading scientists in other countries, undertakes international collaborative epidemiology, prevention, and clinical trials studies and develops bilateral agreements with foreign governments. All other foreign activities at the NIH are conducted under the authority of the Secretary. NCI international activities include:

The execution of a bilateral agreement with the Union of Soviet Socialist Republics (USSR) which was initiated by President Nixon and General Secretary Brezhnev in 1972. Currently, agreements are in effect between the U.S. and Japan, Egypt, France, Poland, the Federal Republic of Germany, Italy, China and Hungary;

support to international agencies concerned with cancer including the **International Agency for Research on Cancer (IARC)** and the **European Organization for Research on Treatment for Cancer (EORTC)**;

the conduct of epidemiologic studies and investigations of the effects of diet on cancer and the ability of micronutrients to reduce incidence in defined populations in other countries including China and Finland; and

the cosponsorship of the **EORTC Research Training Program** which allows exchanges between the U.S. and EORTC member nations. A similar program is being started with Japan.

Foreign travel is controlled by strict ceilings, imposed externally. Effective management of these programs and the conduct of cancer and AIDS research in other countries requires that NCI scientists travel abroad. Foreign travel should be controlled by program requirements and budget availability.

**Recommended legislative change:**

Exempt the NCI from externally imposed foreign travel ceilings beyond those naturally imposed by budget levels to facilitate effective utilization of this authority.

## III. THE GOVERNANCE OF SCIENCE AT THE NATIONAL CANCER INSTITUTE

Because of its size and complexity, and its unique programs and mandates, the National Cancer Institute has required an organizational structure not only different from, but neither required, desired, or appropriate for other NIH Institutes. Using the provisions of the National Cancer Act, NCI has developed a **system of boards** which includes the **President's Cancer Panel** and the **National Cancer Advisory Board**, both appointed by the President, and the four **Boards of Scientific Counselors (BSCs)** to the four NCI program divisions responsible for research in cancer biology, causation, prevention, detection, diagnosis and treatment as well as the **Frederick Cancer Research Facility Advisory Committee (FCRFAC)**, appointed by the Director, NCI. (6)

The BSCs and the FCRF Advisory Committee have been vested, by NCI, with the requisite authorities to serve as effective monitors of program development and implementation within the context of a rapidly changing scientific environment. The BSCs, each chaired by one of the appointed members, are charged with reviewing and advising on both intramural and extramural programs. This range of responsibility exists only at NCI which has consolidated management of related intramural and extramural science programs within each division.

Since 1980, each of the four NCI Board of Scientific Counselors has:

-been chaired by one of its own members;

-held its meetings in public;

-conducted an annual review of the entire divisional budget;

-performed concept review for each new and recompeting contract support project prior to the solicitation of proposals;

-performed concept review for Request for Applications for grant supported projects;

-provided advice on management problems of the division;

-conducted scientific peer review of all of the 58 laboratories and branches in the intramural program through a process of site visits similar to peer review of program project grants;

-provided advice on important areas for future research or the termination of less productive areas of research; and

-sponsored workshops/seminars to facilitate the dissemination of scientific information.

For example, the BSC for the Division of Cancer Treatment was heavily involved in the 1978 development of a Master Plan for Drug Development and a Memorandum of Understanding with the FDA and an FDA-approved NCI distribution system for anti-cancer drugs which is more fully described in Appendix 5. The BSC is currently working with the Commissioner of Food and Drugs to discuss the process for approval of marketing of cancer drugs, a problem recognized by the Yarborough Committee. The BSC proposed, in conjunction with the treatment research community, new approval criteria.

The BSC of the Division of Cancer Etiology reviews the concepts for division agreements with the National Institute of Occupational Safety and Health, the Environmental Protection Agency and the National Oceanic and Atmospheric Adminstration. Individual BSC members also serve on special advisory committees to other agencies on occupational carcinogens.

The Interface

The Panel, Board, and BSC/FCRFAC all have specific roles, and each relates to the other. The BSCs, whose members are selected for their expertise in the areas of science supported by the division, advise on specific intramural and extramural undertakings, prioritizing competing projects for resources within the division, and annually present their deliberations/advice to the National Cancer Advisory Board. Taking into consideration input thus received from the divisional Boards of Scientific Counselors, the NCAB is able to advise the Director, NCI, on policy regarding major program and administrative issues and resource allocation among competing priorities across the Institute. Through regular attendance at NCAB meetings, as well as its own meetings both in Bethesda and nationwide, the Panel is able to monitor the National Cancer Program and to ascertain any blockages or delays in its execution which may be reported by the advisory boards or uncovered through public meetings held at the major cancer centers across the Nation.

This interlocking network of communications amongst the Panel, NCAB, and Boards of Scientific Counselors, culminates at the annual Program Review meeting of the NCAB when the plans for the entire NCI program are examined. At this time the BSC Chairs report to the Board and

Panel on their activities in the past year and plans for the coming year. This Program Review provides a single, comprehensive overview of all the programs of the NCI, their balance and interrelationship and assists the NCAB in recommending budget allocations for the Institute as a whole and in identifying gaps. (6)

The Director, NCI with his Executive Committee, is responsible, under the National Cancer Act, for acting on this guidance and for the execution of the National Cancer Program. The independence granted to the NCI reduces unnecessarily duplicative review of scientific decisions at levels of government both removed from the actual science and/or lacking the necessary extensive and open advisory structure, developed by NCI, required to operate a complex organization like the National Cancer Institute.

From their inception, the Panel, the Board, the Boards of Scientific Counselors and the FCRF Advisory Committee have played a major role in solving problems related to the National Cancer Plan, Cancer Centers, the Frederick Cancer Research Facility, the Biological Response Modifiers Program, redirection of the Cancer Prevention Program and transfer of the Bioassay Program, the human tumor cell line screen, the supercomputer facility, and the Goals for the Year 2000, among many others.

## IV. CONCLUSION

The extraordinary scientific advances from basic research, the resultant opportunities they offer to develop prevention strategies, the increasingly sensitive diagnostic procedures, and the new treatment approaches developed since 1971, more than justify the creation and maintenance of the National Cancer Act. The architects of the Act may be fairly credited with saving hundreds of thousands of lives.

The Act mandated an investment and the means to accelerate basic research and to apply the results of that research insofar as feasible and as quickly as possible. A case study of the NCI which was commissioned by the Institute of Medicine in 1984 as part of its overall study of the NIH concluded (Appendix 7):

> **As a result of NCI's broad mandate to support research on the cause, prevention, and treatment of cancer in the 1937 Act, and its additional authority to plan and develop a National Cancer Program following the 1971 Act, the NCI has been extremely adaptive in using a variety of administrative and funding mechanisms to meet its Congressional mandates. The NCI has emerged into an expanded, coordinated international cancer research and control program that supports a significant amount of basic research, training, and demonstration of advanced methods of controlling cancer.**

Through its special authorities, the NCI has been able to establish a nationwide coordinated network to apply the results of basic research. Today the network includes Cancer Centers, trained physicians, an expanded Clinical Trials Program, the Cooperative Group Outreach Program, the Community Clinical Oncology Program, the Cancer Control Program, Physician Data Query (PDQ) and the Surveillance, Epidemiology and End Results (SEER) program to collect data on cancer incidence and survival.

The Yarborough Committee showed exceptional wisdom and foresight in anticipating that the conquest of the fearsome group of diseases we call cancer would require a coordinated program that went far beyond what had previously been attempted and that the traditional structure and mandates of other NIH institutes would not suffice. They weighed the risk to NCI's ability to meet the challenge and risk of being an atypical institute within the NIH. Wisely, the framers of the Act judged the benefits of remaining within the NIH, for both the NCI and the NIH, would outweigh any disadvantages.

The compromise was a good one. The 1971 National Cancer Act has been reauthorized in 1974, 1977, 1978, 1980 and 1985. Minor changes have accompanied each reauthorization, while the major authorities and mandates have remained unchanged. The Act is an extraordinary experiment in biomedical science that is a model for the management of the highest priority research initiatives. It has served the nation and the research community well for 16 years and has brought us to the point originally envisioned by its framers.

Because half of all cancers occur in people 65 and older, the aging of the population and the successes in controlling heart disease will make cancer the number one health problem in the United States. By the beginning of the next century, it will kill ten times more people in a year than AIDS has killed in five years. This will happen despite the major progress that has been made in research and treatment over the past 16 years and even if the Institute attains its Goal for the Year 2000 of reducing the mortality rate from cancer by 50 percent.

Because of this pressing need, the National Cancer Program requires the continued mechanisms and authorities that the 1971 National Cancer Act set in motion.

# National Cancer Institute
## Percentage Growth FY 1970-1988

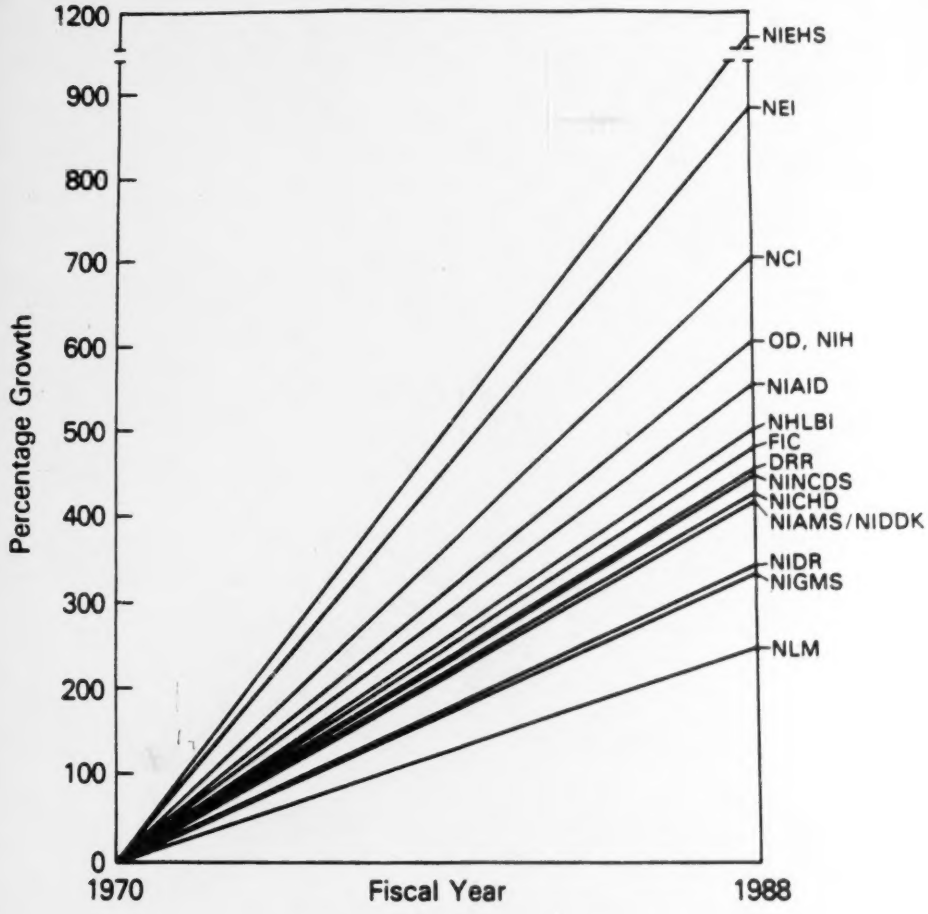


Figure 1

## National Cancer Institute
**Percentage Growth FY 1970-1979**

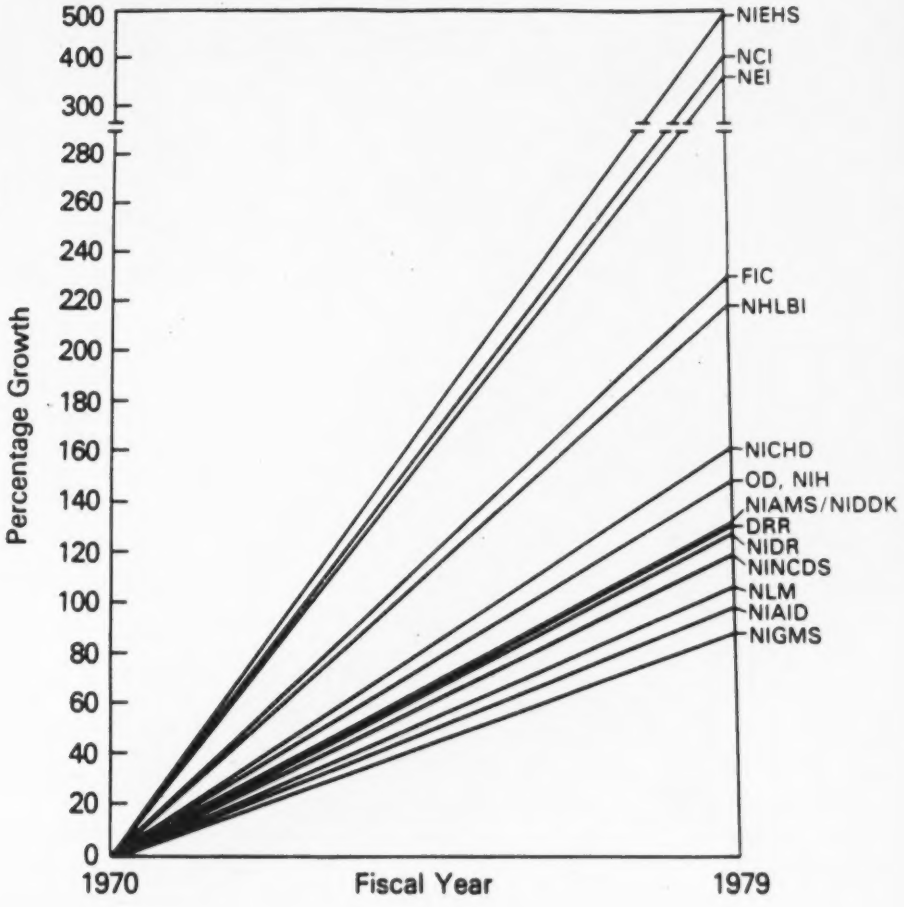


Figure 2

## National Cancer Institute
**Percentage Growth FY 1979-1988**

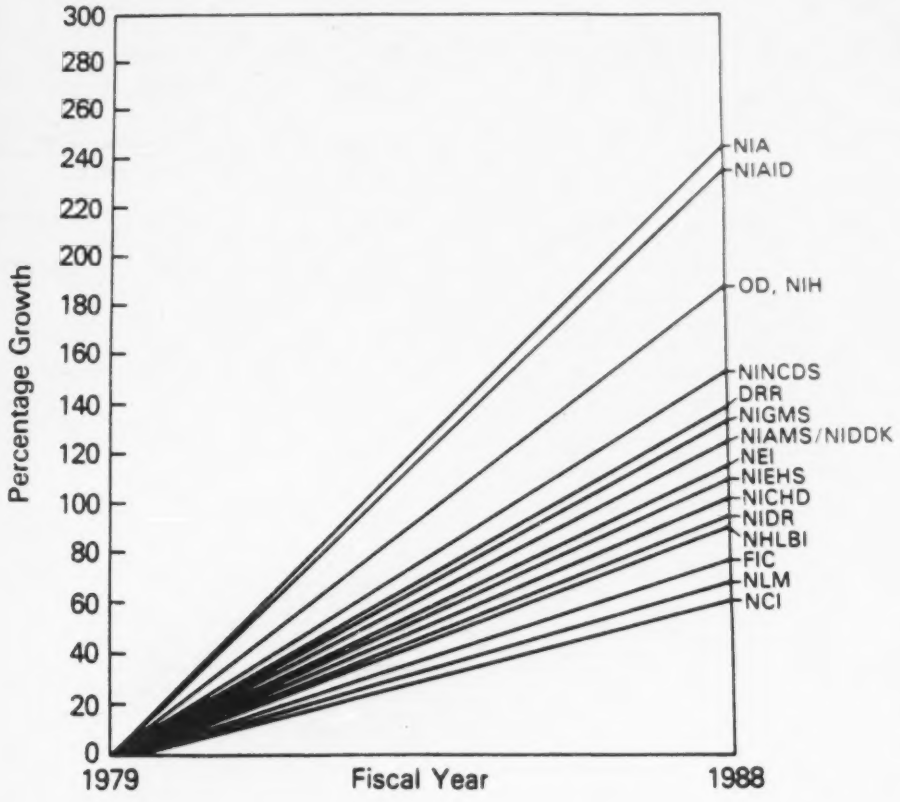


Figure 3

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# STATEMENT

OF THE

ASSOCIATION OF AMERICAN MEDICAL COLLEGES

on

S. 2222

The National Research Institutes

Reauthorization Act of 1988

Submitted to

the

Senate Committee on Labor and Human Resources

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Association of American Medical Colleges / One Dupont Circle, N.W. / Washington, D.C. 20036 / (202) 828-0525

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The Association of American Medical Colleges (AAMC) appreciates this opportunity to comment on S. 2222, the National Research Institutes Reauthorization Act of 1988." The AAMC represents all 127 accredited U.S. medical schools and their students, 435 teaching hospitals, and 85 scientific and professional societies, whose members participate in the biomedical research supported by the National Institutes of Health (NIH). In fact, over half of the extramural research funded by the NIH is conducted in the institutions represented by the AAMC.

We commend the Committee for its thoughtful revisions of Title IV of the Public Health Service Act, including the necessary renewal of the expiring authorities under the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the medical library assistance program of the National Library of Medicine (NLM), and the National Research Service Award (NRSA) program. In this era of important new research opportunities, it is essential that these programs be provided with adequate authorization levels to allow for the necessary growth to take full advantage of these opportunities.

Of particular importance to the Association is the NRSA program, which provides valuable research training support for the next generation of biomedical and behavioral scientists. Based on separate analyses by the NIH and the AAMC Division of Biomedical Research, we endorse the $350 million authorization level contained in S. 2222 for the NRSA program for FY 1989. We understand that this level of funding will provide support for approximately 13,465 trainees, as recommended by the National Academy of Sciences/Institute of Medicine Personnel Needs Study. In addition, funds

would be available to provide payment of full tuition for predoctoral trainees and to increase the stipends to $8,500 a year for predoctoral and to an average of $24,450 a year for postdoctoral trainees, as recommended by NIH. It is important that sufficient funding be available to increase stipend levels without reducing the number of trainees.

Research Facilities Construction

The AAMC, having endorsed the recommendations made earlier to this committee by Chase N. Peterson, M.D., President of The University of Utah, on behalf of the AAU and NASULGC, supports the biomedical & behavioral research facilities construction authority in Title I of the S.2222. The research infrastructure in our universities and medical schools is in critically poor condition. Aging and obsolete research buildings and out-moded instrumentation are beginning to jeopardize our ability to conduct preeminent biomedical research and to maintain our international superiority in biomedical science. Title I of S. 2222 recognizes the critical need for revitalization of our research facilities and reaffirms the appropriateness of the federal role in maintaining and expanding the academic research infrastructure.

The federal government, through the NIH, has been an unparalleled source of support for the biomedical research conducted in the nation's medical schools and teaching hospitals. Academic medicine's partnership with the Federal government in this area has led to dramatic advances in the improvement of health and the conquering of disease and premature death. While the federal support for biomedical research grants continues, the government's commitment to maintaining the facilities component of the

research infrastructure has been virtually non-existent for the past 20 years. Given that so much of the research being conducted in our institutions is sponsored by NIH, it is reasonable to expect that NIH should also contribute to the cost of the space needed to house the research.

The AAMC has developed a model to estimate the financial need to keep current academic research facilities "in shape." The details of this analysis were presented to a group of outside experts convened by NIH, at Congress' request to explore the research facilities deficit. It was also appended to Dr. Peterson's testimony to this Committee. In our estimation an annual investment of $301 million is needed simply to maintain the existing inventory of research facilities. Research space in most institutions is used so intensively, and is at such a premium, that it is not really adequate for existing programs. If we hope to expand biomedical research endeavors in order to make advancements against emerging health crises and intractable health problems, new and modernized facilities will be essential.

The facilities in our institutions have not been able to keep pace with the expansion in biomedical research primarily because funding mechanisms for construction costs are inadequate. Tax-exempt borrowing and charitable contributions, previous sources for private universities, were seriously constrained by the 1986 Tax Reform Act. Moreover, the mechanism of indirect cost reimbursement does not necessarily result in a full recovery of costs.

The construction authority in S. 2222 will begin to address the critical need to remodel, replace, and enhance the current biomedical research infrastructure. It will enable NIH to reembark on a systematic, coordinated approach to meeting facilities' needs around the country. Several essential components of a facilites program are contained in S. 2222, including a matching formula, a merit review requirement, and criteria for determining grant awards.

By acknowledging the appropriateness of the federal role in biomedical research facilities construction, S. 2222 will begin to correct a long-neglected area of federal responsibility. A renewed federal partnership in maintaining the total research infrastructure will help ensure the preeminence America's biomedical research enterprise in the years to come.

Research Centers

Given the existence of the new general construction authority in Title I, the AAMC questions the need for a separate authority in Title VI of the bill for the National Center for Nursing Research. We are concerned that a separate construction program will duplicate, and draw funds away from, the general construction authority. The facilities needs of nursing research programs should compete on an equal footing with the facilities needs identified in other areas of biomedical and behavioral research.

The AAMC supports Titles III and IV of S. 2222 to develop or expand centers for the study of deafness and other communicative disorders within the National Institute of Neurological and Communicative Disorders and

Stroke and centers for geriatric research and training within the National Institute on Aging. Support of such centers recognizes the need for an increased research capacity in these areas, including the need to train additional scientists to develop and pursue promising research leads. With respect to the geriatric centers, the AAMC believes that the "educational and training activities for students of the health professions" specified in Title IV will not duplicate, but rather will enhance, the existing health professions education programs for geriatrics under section 788[e] of the Public Health Service Act.

Fetal Research

Regarding Title II, the AAMC supports the several steps the legislation takes to reactivate national discussion and consideration of ethical matters relating to fetal research. At the same time, we are opposed to the two-year extension of the statutory moratorium on the ability to exercise the waiver of the regulations governing Federally funded fetal research.

The federal regulations pertaining to the conduct of fetal research were established in 1975, and were based on recommendations made by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The regulations ensure that pregnant mothers and babies will be able to benefit from biomedical science's ability to understand human development and conquer the diseases which can deprive fetuses of the chance for life and health. With equal force, they ensure that fetal research conducted with federal funding adheres to a strict moral code and ethical standard of respect for human life. The regulations

uphold the dignity and moral status of individual persons and fetuses while enabling society to fulfill its natural and profound urge to save and enhance life.

Two essential components of the federal regulations, the Ethical Advisory Board (EAB) and the HHS Secretary's authority to waive the regulations in extraordinary circumstances, have been suspended since 1980. Activated for the first time in 1978, the initial EAB existed for only two years. In that time, it approved one waiver of the regulations. Since the charter of the first EAB expired in 1980, the Board has never been reactivated. In 1985, Congress placed a three-year moratorium on the use of the waiver and mandated a study of the ethical implications of the waiver authority.

These de facto and de jure restrictions have caused the fetal research regulations to lose the careful moral balance they were designed to maintain between the pursuit of fetal and maternal life-saving advancements and the safeguarding of human research subjects. The result has been a diminution of federal support for fetal research and widespread confusion about federal laws and rules governing it.

It is incumbent upon the Congress to restore the federal commitment to fetal research and the advancements in fetal and maternal health it makes possible. Restoring the commitment requires the reactivation of the Ethical Advisory Board coupled with the lifting of the moratorium on the waiver authority. Because S. 2222 establishes an EAB without lifting the moratorium, it will fail to restore the commitment.

When Congress enacted the three-year long prohibition of the waiver authority in 1985, it did so with the intention of appointing the Biomedical Ethics Board and Advisory Committee to study the "nature, advisability, and biomedical and ethical implications of exercising any waiver" of the federal regulation that holds non-therapeutic fetal research to the minimal risk standard established for human research subjects. The Biomedical Ethics Advisory Committee has not been appointed and, perforce, the ethical issues and concerns that led to the moratorium have not been explored.

In our view, the ethical issues and concerns that have cast such doubt on the waiver authority are misplaced. The waiver is, in effect, a safety valve which enables federal research to be responsive and adaptive to extraordinary developments in medicine and human biology. A researcher's ability to seek a waiver means that consideration can be given to a project which may be of indeterminate risk but hold overwhelming promise of improving health and the chances for life.

A project cannot receive a waiver without undergoing a painstakingly careful ethical and scientific examination. The examination entails six levels of review and approval beginning with a local Institutional Review Board. Federal level review is conducted by the relevant NIH Study Section and National Advisory Council and the appropriate Institute staff and Director. If the research proposal is cleared at these levels, it advances to the Ethical Advisory Board. The EAB uses strict review criteria in assessing the risks and benefits of the research proposal and ensuring that

no other means exist by which the benefits could be obtained. The EAB deliberates in public and may solicit public comment and consideration of the proposal. If the EAB approves the research proposal, the final decision to approve or disapprove the project rests with the HHS Secretary. In making a determination about waiving specific requirements of the regulations, the Secretary must be certain that the risks to the subject are far outweighed by the sum of the benefits to the subject, that the importance of the knowledge to be gained warrants the use of the waiver, and that the benefits can only be gained through the waiver. The approval of the waiver must be published as a public notice in the Federal Register. Clearly, the waiver authority is a complex mechanism which is employed only after rigorous review and public deliberation. It enables reasoned ethical consideration to be given to research proposals which may not be able to meet all the requirements of the regulations but which hold the promise of such significant benefit to fetal and maternal health that ignoring the potential would leave society morally bereft.

The AAMC believes the positive steps S. 2222 takes in helping to advance public understanding of the ethical issues involved in federally-funded fetal research alone cannot restore the much-needed federal commitment to research in fetal and maternal health. Mandating the establishment of the Ethical Advisory Board and supporting a new effort to examine issues in federal fetal research cannot make up for the fact that the extension of the moratorium on the use of the waiver authority will set back for another two years any possibility of significant federal involvement in the effort to advance important new life-saving and life-enhancing procedures and therapies for fetuses and pregnant women.

Rehabilitation Research Center

A second area of concern to the AAMC is the proposal for a National Center for Medical Rehabilitation Research in Title V. While the AAMC enthusiastically supports the coordination of federal efforts in the area of medical rehabilitation research, we do not agree that the proposed structure is the best method of accomplishing this goal. This proposal appears to go far beyond a coordinative function. Indeed, the stated purpose of this Center in Title V is "the conduct and support of biomedical and related research and research training...." It is unclear from the proposal what type of research would be supported, and how such research would relate to existing rehabilitation research programs within the other national research institutes or other federal agenices, including the Veterans Administration and the Department of Education's National Institute of Disability and Rehabilitation Research. In addition, the current fiscal climate raises serious questions as to how this Center would be funded if it undertakes to support such research.

If the goal is to coordinate existing federal research efforts in the area of medical rehabilitation, the AAMC recommends that the coordinating committee consisting of representatives from the appropriate research institutes and other federal agencies be established, as proposed in section 486E of the bill. This committee could be charged with responsibility for developing the national research plan to coordinate existing research and develop future priorities.

The AAMC appreciates this opportunity to comment on this legislation, and would be pleased to work with the Committee staff to provide additional information on the positions contained in this statement.

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**STATEMENT OF**

**THE AMERICAN ASSOCIATION OF DENTAL SCHOOLS**

**AND THE**

**AMERICAN ASSOCIATION FOR DENTAL RESEARCH**

**SUBMITTED FOR THE RECORD TO THE**

**COMMITTEE ON LABOR AND HUMAN RESOURCES**

**UNITED STATES SENATE**

**APRIL 13, 1988**

This statement on the facilities and training needs of dental research institutions is presented on behalf of the American Association of Dental Schools (AADS) and the American Association for Dental Research (AADR). The American Association of Dental Schools represents all of the dental schools in the United States as well as advanced education institutions, hospital dentistry, and dental auxiliary education programs. It is the only national organization concerned exclusively with the needs of dental education. The American Association for Dental Research (AADR) represents over 4,000 scientists from a variety of basic and clinical disciplines working in universities, research institutes, hospitals, and industrial laboratories around the country.

In this statement we will briefly describe the current research facilities and training needs of our institutions, highlight some concerns unique to dentistry, and identify reasons why a federally sponsored effort to meet these needs is critical.

## RESEARCH FACILITIES

### 1. Need for Improved Facilities

We are aware that the National Science Foundation (NSF), in response to Congress's request, is conducting a survey "to collect and analyze data on the availability, condition, need, cost, and funding sources of science and engineering research and development facilities at colleges and universities." We understand that, at the request of the National Institutes of Health (NIH), the survey will also include non-profit research institutions and independent hospitals. While that survey may reveal a sampling of dental facilities needs, we are concerned that it will not sufficiently illustrate the unique needs of dental research institutions.

For this reason, and because we wish to update currently available data to determine the impact that the deterioration of research facilities is having on the dental research enterprise, the AADS and the AADR are coordinating a national survey of the facilities needs for dentistry. Using a format similar to the one developed by the NSF/NIH for medicine, we will determine the impact of the deterioration of research facilities on the dental research enterprise. The results of this survey, which are expected to be published later this spring, will provide valuable information to those making future policy decisions about the federal role in this area.

In February, 1988, in a preliminary study, we contacted a sample of our member institutions. The responses we received, together with information gathered from a survey conducted two years ago, firmly support the need for a federal facilities program.

In November, 1985, we found that 67% of the institutions responding to our survey indicated a need to expand or renovate their facilities. In February, 1988, our mini-survey showed that the problem has only worsened in the intervening two years, with 77% of the respondents reporting inadequate facilities. Over 40% of the research facilities currently in use reported a need of major repair or renovation. An additional 37% were either in need of repair or were otherwise not suitable for the most sophisticated research in the field.

These numbers only measure the need for expansion and renovation; they do not reflect the pressing need many institutions have to build additional facilities. We will soon have additional information to share with the Committee on this significant part of the research facilities need.

Because most dental research includes clinical trials --or at least testing of the clinical application of the laboratory finding-- our institutions have unique needs for special fixed equipment and facilities. Examples of clinical applications in dentistry include testing diagnostic imaging techniques and testing dental materials. When asked specifically about their clinical research facilities, over half of the members we surveyed in February, 1988 classified them as inadequate.

**2. Causes of the Need for Improved Facilities**

Among other factors, recent requirements concerning the proper handling of hazardous materials, radioactive waste disposal, and isolation of toxic agents used in virology research have exacerbated the basic facilities problem that has existed for some time. New renovation needs have been created even for those institutions that have recently remodeled their older laboratories. The rapid expansion of AIDS research in dentistry has resulted in a pronounced emphasis on virology and immunology, creating a corresponding change in facilities demands.

While many of our institutions have indicated plans to upgrade their facilities to address the needs we have discussed, they must wait--often for years--for approval of proposals to finance their renovation projects. Even those who have succeeded in securing state, institutional or private funds have found these sources to be limited. The money that is available generally can support only small repair or maintenance projects; it is not sufficient to fund the upgrading and renovation of facilities that is necessary. Similarly, where it is possible for institutions to use tax-exempt bond issues to finance construction projects, the overall needs of the institution frequently overshadow the facilities needs of the research sector.

We understand that all disciplines are suffering financial difficulties; however, we believe that the situation is especially acute in dentistry. Dental schools do not receive federal support for the expenses they incur in operating their clinics, the locus for the practical applications of dental research. In fact, these clinics are already heavily subsidized through tuition, which combined with state and local funding, makes up over two-thirds of dental school financing. Thus, our members have limited flexibility in redirecting any of the remaining revenue they receive into needed renovation of their clinic facilities.

**3. Federal Role in Supporting Dental Research Facilities**

Historically, federal support for construction and renovation of facilities has been a part of this country's commitment to the biomedical research enterprise. In response to a post-war expansion in biomedical research, a facilities construction authority was established in 1956 to provide the physical structures needed to house the growing enterprise. In the 1960's, legislation was enacted to assist in the construction of health professions teaching facilities; eligibility for these grants was later extended to facilities conducting health research.

In the past, the National Institutes of Health (NIH) supported facilities construction through grant programs and subsidized loans, but there has been virtually no federal money available for research facilities since the early 1970's.

Unfortunately, dental research institutions have not had the resources to make up for the lost federal revenue, nor is the National Institute of Dental Research (NIDR) in a position to address the facilities problem without additional federal resources. In fact, the current budget situation requires routine downward negotiation of NIDR grants, and does not allow for training stipends that are comparable with other scientific disciplines. The absence of a federal facilities initiative means that our institutions are falling further and further behind in paying for maintenance that has been deferred for years, and in meeting the demands imposed by the new directions in dental research.

We are pleased that Congress has directed the NIH to investigate the feasibility of a pilot research facilities program to assist biomedical research institutions in replacing obsolete facilities and equipment. We believe this is an important first step toward responding to the current need for renovation and repair of the extramural facilities where NIH-sponsored research is underway. It is crucial that this program be supported with <u>new</u> funding, and not, as has sometimes been proposed, be paid for with funds that would otherwise be used to support the research itself.

The AADS and the AADR support a matching grant program for research institutions to use in modernizing and expanding facilities. While we would expect that any proposed remedy will be NIH-wide, we request that the NIDR be specifically consulted concerning the clinical facilities needs unique to dental research institutions.

**NATIONAL RESEARCH SERVICE AWARDS**

**1. Number of Dental Trainees**

In its 1985 study, the Institute of Medicine's (IOM) Committee on National Needs for Biomedical and Behavioral Research Personnel found that dental research had not kept pace with developments in other clinical science sectors, and noted that dental research personnel levels had fallen precipitously since 1980. The IOM study emphasized that the NIDR is essentially the only sponsor for the training of dental investigators, and recommended that the number of positions supporting dentists be increased to 320 by the year 1990.

In fiscal year 1986, however, only 90 National Research Service Award (NRSA) trainees were dentists. Thus, an additional 230 trainees would be needed to reach the level recommended by the IOM. In order to meet the documented need and demand for dental school faculty with research training, the AADS and the AADR recommend that the funding for the NRSA program be increased to provide for a substantial increase in the number of trainee positions available.

**2. Amount of Stipends**

A related problem is that stipend levels of NRSA trainees are currently set at unrealistically low levels. The "steps" up the sliding scale of awards --based on number of years of relevant postdoctoral experience-- are much too low. Stipends range from a starting salary of $15,996 for a trainee just out of dental school, to the maximum of $30,000 for a trainee with seven or more years of postdoctoral experience.

Thus NRSA traineeships provide roughly half the income which potential trainees could earn in other pursuits. For example, a dental graduate beginning practice in 1985 earned a salary of approximately $35,000, and the average practitioner out of school for seven years earned about $60,000.

Offering such low stipends, institutions have difficulty in attracting talented dentists into research. This problem is exacerbated by the sizable student loan debts most dental graduates must repay.

NRSA stipends cannot be supplemented with other federal funds; however, institutions often subsidize trainees with their own

funds. This practice is costly to the research institutions, and has had the effect of limiting the program to low-level positions.

Without question, there should be a significant increase in the stipend levels allowed under the NRSA program.

The AADS and the AADR believe that an increase in both the number of dental research trainees and an increase in the stipends received by these investigators is critical to the research training effort of the NIH.

**BIOMEDICAL SCIENTIFIC SERVICE**

Provision should be made to attract and retain senior research scientists at the National Institutes of Health by providing adequate remuneration for those who have distinguished themselves in biomedical research. A few such outstanding scientists are presently collaborating with researchers at the National Institute of Dental Research, analyzing data gathered through the recent epidemiological survey of adult dental status. The involvement of these distinguished researchers with the NIDR is, however, limited to that which can be accomplished during a sabbatical, as the salaries available to NIDR scientists fall far short of what would be needed to recruit them on a full-time basis.

We understand that similar experiences occur throughout the NIH. The AADS and AADR support the establishment of a senior biomedical scientific service to begin to address this problem.

We appreciate the opportunity to present our concerns to you at this time, and would be pleased to respond to any questions concerning our testimony. Our Associations look forward to increased involvement in the promotion of dental research for the benefit of all Americans.

FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

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# STATEMENT OF DR. ROBERT W. KRAUSS

Executive Director of the

FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY

on

BIOMEDICAL RESEARCH FACILITIES CONSTRUCTION

NATIONAL INSTITUTES OF HEALTH
FEBRUARY 9, 1988

PUBLISHER OF THE FASEB JOURNAL

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Dr. Wyngaarden, distinguished panelists, thank you for the opportunity to discuss the Federation's views on the state of the nation's biomedical research facilities. I am Robert W. Krauss, executive director of the Federation of American Societies for Experimental Biology.

FASEB is a nonprofit organization whose purpose is to develop and disseminate new knowledge in the life sciences through its meetings, publications and programs. The Federation's more than 29,000 members are scientists who represent research, educational and clinical centers throughout the U.S. We count 110 Nobel Laureates from among our membership since FASEB was founded in 1912.

NIH has gained a deserved worldwide reputation as a leader in biomedical research. Its investigators turn out valuable findings and discoveries each year--discoveries that have led to the treatment, cure and prevention of diseases to the benefit of all mankind.

Absolutely critical to NIH's success is a strong and modern research infrastructure at the nation's research institutions. Without top-notch laboratories and up-to-date equipment, the United States will have difficulty maintaining its international leadership role in biomedical research.

We are pleased that NIH has convened this important meeting, as

requested by the Senate Appropriations Committee. The Senate panel directed NIH to convene a group of consultants to recommend the design, program balance and administration of a pilot research facilities program administered by NIH. The House Appropriations Committee, while not as specific, did ask NIH to review the facilities issue before the FY 1989 appropriations hearings and "to be prepared to discuss the problem including the role of the indirect cost mechanism for financing capital costs."

There is an urgent need to modernize existing facilities and build new ones for biomedical research, as well as in other areas of scientific investigation. As illustrated in studies generated by both Congress and the Administration, it is becoming increasingly apparent that aging and obsolete labs and equipment are hampering research progress.

The Congressional Research Service reported recently that funding for major federal programs for construction of university research facilities declined 85 percent in constant dollars between FY 1963 and FY 1984. It found that total federal funding for such purposes decreased from $325 million in FY 1963 to $45.9 million in FY 1984.

Moreover, the National Science Foundation estimates that half of university physical plants are more than 25 years old and a quarter were built before World War II. In addition, recent surveys indicate that institutions cite life and medical sciences

as areas of great need for updated and new facilities.

The White House Science Council's Panel on the Health of U.S. Colleges and Universities concluded in its 1986 report that if universities are to bring their research laboratories and equipment up to an acceptable level, federal funding would be required. The panel recommended $10 billion over the next 10 years, with $5 billion from the government and $5 billion in matching funds from nonfederal sources.

With the expiration of the 1956 Health Research Facilities Construction Act in 1972, NIH lost its general construction authority. And, currently, only three institutes -- cancer, heart and eye -- have construction authority.

Furthermore, even the existing NIH facilities program has been drastically underfunded. Over the past decade NIH support for construction projects has declined steadily. In FY 1976, some $20 million was appropriated for NIH construction projects. For FY 1988, no money was provided for this purpose.

We believe it is essential that NIH's construction program be restored. Such a program should be adequately funded so as to prevent merely a shifting of resources from existing NIH programs in order to support facilities.

Last year, through the Ad Hoc Group for Medical Research Funding,

FASEB joined with over 100 scientific- and health-related organizations in recommending that NIH's general construction authority be reinstated. At that time, the Group requested funds for repair, renovation and replacement of facilities. To accomplish that task alone, we estimated a price tag of about $550 million annually just to maintain current extramural research facilities. In realizing that such a sum was more than could reasonably be expected, the Group requested a "down payment" of $200 million for facilities in FY 1988.

Additionally, the Ad Hoc Group noted that animal facilities at many institutions need to be improved, particularly in light of the requirements laid out in the recently revised Public Health Service animal care policy as well as further standards imposed by the 1985 Animal Welfare Act amendments. The Group requested $38 million to update animal facilities.

The absence of a research facilities program has forced universities in recent years to approach Congress directly for their much-needed construction money, thereby bypassing the merit review process by which research funds are meant to be awarded. Such congressional earmarking of funds denies many schools and institutions the opportunity to compete fairly for research support.

Creating a special facilities fund could help universities avoid supporting their physical improvement with money intended to carry

out the actual research. It would deal with the research infrastructure problem directly and would not prompt universities to boost their indirect cost pool to cover such expenses. In addition, establishing a facilities program would be a more preferable means of addressing facilities problems than the proposed liberalization of the building use allowance and depreciation rate that schools can charge to indirect costs.

A number of bills aimed at rebuilding the nation's research infrastructure are pending in Congress. Most of the measures, however, are directed toward the variety of science and engineering programs supported by the National Science Foundation. The effort should be expanded to include biomedical research facilities specifically.

In testimony before the House Science and Technology Committee last year, FASEB supported the original facilities bill (HR 1905) sponsored by Representative Robert Roe of New Jersey. We believe that such a program as envisioned in the Roe bill would provide the appropriate starting point for an NIH facilities program, even of the pilot variety. Such a program would ensure merit review, an even distribution of funds, long-term support, adequate funding authority and matching of federal dollars with money from nonfederal sources.

We commend NIH for moving quickly on the Appropriation Committees' requests. Careful examination of the state of the nation's

biomedical research laboratories will enable the panel to come up with solid recommendations for bringing those facilities up to date.

Institutions' physical research plants must be revitalized if the US is to extend the frontiers of science particularly in the new field of biotechnology. Neglecting our facilities would seriously diminish our international competitive position in biomedical research.

Thank you and I will be glad to answer any questions.

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NICHOLAS G. CAVAROCCHI
DOMENIC R. RUSCIO

March 31, 1988

Mona Sarfaty, M.D.
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Dear Dr. Sarfaty:

On behalf of the Conjoint Committee for Diagnostic Radiology, I respectfully ask that the enclosed statement be included in your Committee's March 29 hearing record on the reauthorization of NIH.

Thank you for your time and consideration.

Sincerely,

Domenic R. Ruscio

DR:ks

Enclosure

Mr. Chairman and members of the Subcommittee-

My name is Charles Putman, Professor of Radiology at Duke University, and I am here on behalf of the Conjoint Committee on Diagnostic Radiology.

By way of background, the Conjoint Committee is composed of representatives from the American College of Radiology, the Association of University Radiologists, and the Society of Chairmen of Academic Radiology Departments. The idea of drawing these organizations together for a common purpose was conceived in 1978. And while this is a field noted for the rapid pace of new knowledge and innovations it generates, that common purpose has remained clear and steady: To promote and support the advancement of diagnostic imaging research.

Mr. Chairman, our society has built an impressive health record. Since the turn of the century, we have increased life expectancy by nearly 30 years, or about as much as the gain for the previous 5,000 years. The array of modern drugs, appliances, and surgical techniques available to prevent disease and save lives is impressive in scope and quality.

But each improvement raises our horizons. Each scientific advance highlights the remaining challenges.

Many factors have contributed to that national record of achievement, not the least of which is the tradition of leadership and commitment demonstrated by this Subcommittee.

By the same token, the field of radiology has played a significant role in helping to diagnose and treat illnesses that once threatened society. The fact is that while few may have noticed, radiology has been undergoing a quiet revolution, experiencing more dramatic changes in the past 20 years than any other specialty in the field of medicine. It is now to the point where medical imaging procedures account for, or contribute directly to, the final patient diagnosis in over 75 percent of all hospital admissions.

What is more, at no time in the past has medical imaging offered more opportunities for research that could directly enhance our ability to diagnose disease.

In large part, this rapid evolution and the promise it holds for the future is a result of the advent of new imaging mechanisms such as the CT scan, ultrasound, and nuclear magnetic resonance imaging.

The quiet revolution I spoke of extends well beyond the bounds of a single disease or, for that matter, a single research institute.

The achievements, the promise, and the potential of diagnostic radiology cut across the whole spectrum of medicine and health-- from diagnosing congenital heart disease in infants and children to unraveling the mysteries surrounding dementia. Medical imaging aids in the study and diagnosis of brain tumors, head and neck injuries, musculoskeletal disorders, trauma, and degenerative disc diseases, to name just a few.

During the past year, for example, scientists reported that specific changes in the blood of cancer patients could be detected using magnetic resonance spectroscopy before there was any clinical evidence of tumors. Investigators are now attempting to confirm these preliminary results and to evaluate applications of such a test for detection, diagnosis, and monitoring of therapy.

On another front, scientists are exploring whether ultrasonography used either alone or in combination with biological markers can help diagnose early prostate cancer.

Looking ahead, new technology for creating images of the brain holds out exciting new hope that we may soon have reliable diagnostic tests for Alzheimer's Disease and other forms of dementia.

This new technology can produce a cross-sectional image, or "slice" of the brain or other organs, as opposed to the front to back type of picture produced by an X-ray. These slices reveal precise anatomic information that cannot be obtained by standard X-ray techniques. Taking the slices together, the physician is able to get an accurate three-dimensional image, allowing investigation front-to-back, side-to-side, or top-to-bottom. In addition to producing a visual image, some of these new techniques also produce quantitative data about the characteristics of the tissue being examined.

Few would disagree that diagnostic imaging could hold the answers to many of the diseases and disorders that threaten so many lives. Where we run into a problem, Mr. Chairman, is in moving this new and wonderful technology into the clinical research stage. And as you know, all the new machines in the world will count for little if we cannot put them to use in saving lives.

I should also note that the requirements for research manpower in the radiological sciences have never been as great as at the present time. If we hope to fulfill the promise that new technology lays at our doorstep, we must strengthen the flow of basic and clinical scientists.

Recommendations

To these ends, the Conjoint Committee urges the Labor and Human Resources Committee to consider the following when it begins deliberations over the reauthorization of the National Institutes of Health-

- Encourage the National Institutes of Health to increase the size and number of research grants awarded in the diagnostic radiologic sciences.

- Urge the NIH to place greater emphasis on training, by increasing the number of training slots allocated under the National Research Service Awards and Physician/ Scientist programs.

- Recommend that NIH establish an imaging laboratory, with a view towards developing a strong intramural program in diagnostic radiology.

- Call for the creation of a coordinating committee to serve as a central focus on diagnostic radiology within NIH.

- Encourage the NIH to appoint qualified, distinguished diagnostic radiologists to NIH study sections and advisory councils.

Thank you, Mr. Chairman. I would be glad to answer any questions you may have.

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STATEMENT IN SUPPORT OF FUNDING FOR RENOVATION,

REMODELING, OR CONSTRUCTION OF LABORATORY ANIMAL HOUSING

Before the Committee on Labor and Human Resources

by Christine Stevens, Secretary

March 29, 1988

The Improved Standards for Laboratory Animals (ISLA) amendments to the Animal Welfare Act went into effect December 23, 1986. Although final regulations have not been promulgated, institutions using primates must necessarily recognize the important provision which mandates "an environment adequate to promote the psychological well-being of primates."

Since enactment of the law, a number of institutions have improved housing for primates by such means as joining two cages together, which formerly housed a single primate in each, and allowing two compatible primates to share the double space. The inclusion of a branch in the double cage has been instituted by some institutions and allows expanded activity by the occupants of the enclosure. Photographs show that the branch is often used by the primates. It has also been found that the majority of paired primates have been not only compatible but soon began to groom one another in a friendly manner. Serious students of primate behavior consider social grooming to be the most important bonding activity in primate groups.

The changes I have mentioned obviously do not call for major expenditures. Nevertheless, such expenditures as are required should be supplied in the pending Reauthorization Bill for the National Institutes of Health so that grantees can request the necessary funding for the specific purpose of providing for the psychological well-being of the primate subjects.

The larger and stronger primates are obviously more expensive to house. Leaving them in small, single-occupancy cages would be contrary to the intent of the law. Baboon social organization is complex, as fully documented in the recent book by Shirley Strum, Ph.D., Almost Human (Random House, New

York, 1988). The book chronicles fifteen years of observing a troop of baboons. The foreword, by George B. Schaller, the world famous zoologist, points out: "These animals were most definitely aware of the consequences of their planned acts . . . Like several other recent works, Almost Human recognizes and accepts mental abilities in animals, an important reversal of a scientific trend."

Clearly, such primates require more than a barren cage to promote their psychological well-being. Some institutions may decide to use built-in partitions in rooms which formerly housed cages so that a number of animals can be kept within an enclosure that provides for the possibility of moving out of the view of the group and for a variety of activities.

Again, although the expense may not be very large, nevertheless it should be recognized as a legitimate expenditure for the specific purpose of meeting the provisions of the Improved Standards for Laboratory Animals amendments.

The housing of chimpanzees provides another example in which funds for modifying existing structures or constructing new ones should be available under the NIH Reauthorization Bill. Attached is the recommendation of the workshop on chimpanzees conducted by Dr. Jane Goodall, December 1-3, 1987. Participants in the workshop represented the following disciplines: primatology, anthropology, psychology, zoology, and virology. Those using chimpanzees for medical research and those primarily interested in the welfare of animals were included in the workshop. The recommendations were made to assist the U. S. Department of Agriculture in promulgating Part III of the regulations under ISLA.

Although the number of research institutions using chimpanzees is not large, in some cases an individual institution may house a very substantial number of chimps. Thus, the cost of providing appropriate housing may be substantial. It is important that these funds should be available under the pending bill.

To return to smaller primates, a system has been developed at one institution for regulated release of primates into areas where they can exercise, play, and use their mental capabilities on objects which cannot be kept in small cages. This system, although it does not fully meet the provision of the 1985 law, provides a useful interim measure and is deserving of financial support through NIH.

A variety of other measures which are not excessively

expensive may also arise as institutions use their ingenuity to give their animals better opportunities for normal living.

The Society for Animal Protective Legislation strongly urges that the NIH Reauthorization Bill include the necessary funding to meet the requirements of the Improved Standards for Laboratory Animals Act.

RECOMMENDATIONS TO USDA

on improving conditions of

PSYCHOLOGICAL WELL-BEING FOR CAPTIVE CHIMPANZEES

As currently formulated and applied, federal regulations and guidelines governing the maintenance and care of captive primates used in experimental studies do not adequately address their psychological well-being. A workshop was therefore held on December 1-3, 1987, bringing together a cross-section of professionals experienced in studying both normal and abnormal chimpanzees, to consider this deficiency and to develop sound recommendations on improving the psychological well-being of chimpanzees held in laboratories and other facilities. The collective expertise of this diverse group covered many aspects of chimpanzee behavior and biology, ranging from biomedical research and veterinary care in laboratories to psychological and ethological studies in both wild and captive settings, as well as zoo administration and colony management. Conservation and animal welfare interests were also represented.

Chimpanzees are more like humans -- genetically, physiologically, anatomically, and in the structure and circuitry of the brain -- than are any other living beings. Wild chimpanzees have a long childhood of about 7 years followed by 6 or so years of adolescence during which the skills needed to succeed in adulthood must be learned through experience and from other group members. Lack of opportunity for normal development can severely impair this learning process.

Chimpanzees show many cognitive abilities once viewed as uniquely human. They are, for example, capable of reasoned thought, generalization, abstraction, symbolic representation, and self-awareness. Many of their emotions, such as joy and sadness, fear and anxiety, and even a sense of humor, are highly similar to ours. They also exhibit empathy and friendship, perform acts of true altruism, and mourn the deaths of companions. There are also many similarities in social behavior, including communicative gestures such as kissing, embracing and holding hands. Close, supportive, friendly bonds between individuals are maintained and strengthened, via social grooming and many other relaxed social activities, through spending long hours in one another's company. These relationships last for a lifespan of 40-50 years. Separation from a close companion can lead to marked distress, even among adults. Any youngster less than 5 years in age who loses a mother is likely to become clinically depressed and may even become so ill that death follows. The chimpanzee infant and the human child are alike in many ways, such as their capacity for endless romping and play, their curi-

osity, their ability to learn by observation and imitation, and above all in their need for reassurance and affection.

All professionals attending the December workshop agreed that, in view of the close evolutionary relationship between chimpanzees and humans, this sibling species should receive special treatment when used in the laboratory or when maintained in any other captive situation.

Despite the difficulty of adequately defining psychological needs and states for another species, it was further agreed by those attending the workshop, based on their collective expertise and the best available information, that the psychological well-being of the chimpanzee depended on provision of the following: space for vigorous activities such as running, climbing and swinging to allow adequate exercise; material for making comfortable beds as substitutes for tree nests; frequent social contact with other chimpanzees and human caregivers; opportunity to establish close social bonds in groups of mixed age and sex; variety in basic routine, including diet, social interaction, and object manipulation; and presence of intellectual stimulation and challenge.

It is precisely because chimpanzees are so like humans physiologically that they are used by medical researchers in the attempt to alleviate human suffering and illness. And it is also because they are so like ourselves emotionally, cognitively and behaviorally that we must improve the quality of their lives during those long years of imprisonment and servitude.

In order to assist the USDA in formulating regulations that are in keeping with the spirit of the new legislation on psychological well-being for chimpanzees and other primates held in captive conditions, we offer the following recommendations:

A.GENERAL ISSUES

Scientists intending to perform experiments on chimpanzees must be able to prove, beyond all reasonable doubt, that the experimentation cannot be performed by using a lower species, via non-animal alternative methods, or through carefully controlled clinical research. Chimpanzees should only be used for laboratory research of exceptional importance. All proposals for work involving chimpanzees must be subject to rigorous and independent professional scrutiny, with due consideration of whether similar studies have been undertaken previously or are already in progress elsewhere. Evaluation of the scientific merit of the proposed work and the benefits likely to accrue from it must be set against the likely adverse effects on the chimpanzees to be used. Unnecessary and unjustified duplication of experimentation is scientifically and ethically unacceptable, as are terminal stud-

ies on chimpanzees. Once a project using chimpanzees has been approved by the proper authorites, changes in protocol that potentially affect the psychological well-being of the experimental subjects must be periodically reviewed and reapproved under the same set of standards.

The use of chimpanzees in laboratory research is an international problem, and should not be considered solely in a national context. It is deemed unacceptable for individual scientists, institutions, corporations, or funding agencies to be involved in research on chimpanzees carried out in other countries having lower standards of scientific scrutiny or animal housing, care and acquisition. Moreover, the taking of chimpanzess from Africa for any reason is unacceptable.

Any chimpanzee used once for painful and/or extremely stressful experimentation should be exempt from further experimentation of a painful or stressful nature.

B. PERSONNEL TRAINING

Scientists whose work involves the use of chimpanzees for any purpose must have an understanding of the nature of chimpanzees, so that the effects of experimental protocols on individual chimpanzees can be properly assessed in the course of planning the research.

Caregivers responsible for chimpanzees must receive special training, over and above the standard training required in caring for other laboratory species, including other primates, to fit them for the very special task of attending to the physical and psychological needs of chimpanzees. These special training procedures must be established at every facility housing chimpanzees. Evidence must be provided that training has been undertaken and successfully completed. In addition, a national accreditation scheme must be established, providing for professional certification by the USDA. The National Agriculture Library, in cooperation with the National Library of Medicine, should facilitate training by providing manuals, videotapes and other books and papers that must be read by those working with chimpanzees.

During the selection of caregivers, emphasis must be placed on the qualities of compassion, dedication, and empathy with chimpanzees, in addition to the usual qualifications demanded of such laboratory personnel. The adult chimpanzee to caregiver ratio must never fall below ten to one. With youngsters below the age of 7 years, additional caregivers are required in order to maintain frequent interaction.

The director of any facility must be responsible for ensuring that all institution personnel, including caregivers, are fully

aware of the rules and regulations of USDA Veterinary Services and other pertinent governmental agencies that apply to the maintenance and experimental use of chimpanzees. Any violations of these regulations must be reported to the USDA and any funding agency involved.

C. HOUSING CONDITIONS

Chimpanzees must be kept in compatible groups, at a minimum two individuals together. Separation from close companions typically induces pyschological stress leading to physiological as well as behavioral changes, and in addition to threatening well-being may skew the results of experiments performed on that individual.

Chimpanzees must never be housed singly unless sick and in need of special treatment. If under exceptional circumstances the experimental protocol necessitates single housing, then the scientist must prove the need for this beyond all reasonable doubt. There is no known or justifiable medical or scientific reason for a chimpanzee to be kept in an isolette -- i.e., a chimpanzee must never be maintained without aural and visual contact with other members of the same species, on at least two sides of the enclosure.

Chimpanzees must be housed in areas of not less than 400 square feet, with a minimum height of 7 feet, consisting of two to four inter-connecting enclosures in different rooms. The structure and fur-nishings of the enclosure must provide ample opportunity for vigorous activity as well as privacy, and for varying the size of the social group.

The size of enclosures should increase on a sliding scale as a function of the number of chimpanzees being housed in a group. Two adult chimpanzees require 400 square feet of usable space, but in cases of demonstrated compatibility four adults or six juveniles can be maintained in enclosures of this size. If a scientist can confirm an empirical need for individual housing for experimental purposes, the enclosures must never be smaller than 196 square feet (14 ft. x 14 ft.) with as much height as is reasonably possible within a standard room (minimum 7 feet).

In all newly built facilities chimpanzees must be provided with an outdoor activity area. Chimpanzees should never be confined to rooms without windows through which to view the outdoors.

Existing facilities which cannot immediately comply with the new regulations pertaining to enclosure size must nevertheless provide chimpanzees with exercise rooms of 200 square feet floor area until the abovementioned standards can be fully implemented.

D. ENVIRONMENTAL FACTORS

Chimpanzees must be provided with a variety of occupations and opportunities for object manipulation in the effort to improve their lives of confinement to the greatest extent possible. This must include variety in food items, variation of routine with surprise treats and events, provision of items such as magazines, empty egg cartons, etc. A series of problems solving devices will enable them to work for their food instead of picking it out of a feeder bin. They must be given the opportunity to exercise some control over their environment. As an example, a series of buttons, connected to a computer terminal, can provide, when pushed, a drink, a raisin, a toy, etc. Such machines could be activated at irregular times and the chimpanzees informed by a caregiver or some signal device. Detailed records must be kept of the different enrichment procedures used each day, and made available to USDA (APHIS) inspectors. A regular exchange of information about enrichment procedures should also be promoted among facilities.

Mechanical enrichment devices or procedures, such as those noted above, should not be regarded as substitutes for social activity with caregivers.

Bedding materials, such as blankets, are essential. Young chimpanzees can readily be taught to hand over such items in the morning, for washing, in exchange for, for example, a treat.

Handling procedures such as anesthetization, capture, introductions, moving to new enclosures must be done in ways that minimize stress, fear, and physical harm. For example, chimpanzees living in large cages can be taught to enter smaller separate handling cages for experimental procedures, such as injections. If chimpanzees routinely sleep in small cages attached to the larger enclosures they can then be easily handled in the morning if needed for experimental purposes.

For young chimpanzees, friendly interaction with the caregiver is also of tremendous importance, and must be encouraged on a regular basis so as to develop bonds which help to reduce stress when individuals must be handled in experimental protocols.

The Institutional Animal Care and Use Committee shall establish, in consultation with the attending veterinarian, written procedures and guidelines for ensuring the psychological well-being of primates in accordance with established regulations and standards, and a record system to permit evaluation of compliance.

E. SOCIAL CARE FACTORS

The mother-infant bond is essential to normal pyschological de-

velopment of an infant chimpanzee. In addition, relationships with other chimpanzees during infancy lead to the acquisition of normal social and parental skills. Therefore, every effort must be made to raise infants in multi-mother groups that also include compatible adult males.

Infants must remain with their mothers as long as possible, at least to the age of 18 months. If earlier separation is necessary because the mother is unable to care for the infant, fostering of the infant to another lactating female should be attempted. If that is not possible, the infant must be placed with compatible youngsters of similar age. Infants under the age of 18 months who are separated from their mothers and raised by human caregivers must receive individual care around the clock for several months. When mother-infant separation is required by experimental protocol, this should be done so as to provide time for the gradual transfer of emotional attachment from the mother to the human caregivers.

Youngsters of any age who are separated from their social groups for use in any experiment must be given a minimum period of 3 months for adjustment to their new conditions, before placement in any experimental situation.

Careful attempts must be made to reunite juveniles and infants with their mothers in their original social group at the completion of experiments.

F. RELOCATION

The transfer of chimpanzees between research facilities should be avoided unless absolutely necessary. If it becomes necessary to relocate individuals or groups, then chimpanzees should be accompanied by a familar caregiver who must remain with them until they have begun to adjust to the new facility and formed new affinitive attachments with the new caregivers.

G. RETIREMENT

Chimpanzees who are no longer useful to biomedical research must be retired and when necessary rehabilitated so that they may live out their lives in conditions that guarantee their psychological well-being until they die of natural causes. No research projects involving the experimental use of chimpanzees should be initiated without prior guarantee of adequate funding to endow a program of retirement designed to provide normal lifetime support for each subject.

H. SCHEDULE OF IMPLEMENTATION

In order to comply with these standards, it is expected that all facilities housing chimpanzees will require extensive modification. Implementation of the new standards in a graded sequence, with some changes expected to occur immediately while others may require months or years to complete after publication of the new regulations. All facilities must submit their plans for implementation within six months to the USDA. Basic enrichment programs which involve little or no cost should be implemented immediately. Temporary improvements to existing enclosures, such a joining tunnels and exercise rooms, must be implemented within one year. More extensive reconstruction or erection of new enclosures must occur within five years. Construction projects that are currently underway must be immediately modified to conform to the new standards.

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Washington, D.C.

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Senator HARKIN. Thank you all very much. The Committee will stand adjourned.

[Whereupon, at 5 p.m., the Committee was adjourned.]

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